Navigating Conflicts of Interest in Academia

Bryn Williams-Jones, Sihem Neila Abtroun, Charles Marsan

Summary

In today's academic landscape, universities and their researchers are increasingly entangled in financial partnerships with private and public entities, raising concerns about potential conflicts of interest. These alliances, though not new, have gained significance in recent decades, prompting a closer examination of their impact on academic objectivity and credibility. Although much attention has been devoted to financial conflicts of interest, particularly in fields like clinical research, other sources of competing interests in academia have been comparatively overlooked. This book fills that gap by exploring various facets of conflicts of interest beyond financial considerations, such as student-professor relationships and peer review processes.

Bringing together the results of more than a decade of research conducted at the Université de Montréal, this book offers insights into conflict-of-interest management policies and practices. It addresses the varying regulatory approaches across institutions and emphasizes the importance of not only establishing clear policies but also fostering a culture of ethical awareness and compliance.

Structured into three parts — 1) *Professors and Students*, 2) *Research and Publication*, and 3) *Institutional Policies* — the book provides practical resources for university stakeholders. Each section features case studies, conceptual analyses, and policy discussions to aid professors and senior managers in identifying, evaluating, and managing conflicts of interest effectively. The aim is to offer tools that can enhance understanding of conflicts of interest and support the implementation of ethical practices in academia.

About the Editors

Bryn Williams-Jones is Professor of Bioethics and Director of the Department of Social and Preventive Medicine in the School of Public Health at the Université de Montréal. He is interested in the socio-ethical and policy implications of health innovations in diverse contexts. His work examines the conflicts that arise in academic research and professional practice with a view to developing ethical tools to manage these conflicts when they cannot be avoided. Prof. Williams-Jones is Editor-in-Chief of the Canadian Journal of Bioethics / Revue canadienne de bioéthique; in his bilingual blog BrynStorming, he shares his ideas on academic life.

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The book examines conflicts of interest in academia, focusing on issues beyond financial considerations, such as student-professor dynamics and peer review. Drawing on over a decade of research, it offers practical insights, case studies, and policy recommendations to help academic stakeholders foster ethical awareness and more effectively manage conflicts of interest, wherever they arise.

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Published in Canada, 2026
Conflict-of-Interest Research Group
École de santé publique de l'Université de Montréal
7101 ave du Parc, Montréal, Québec, Canada, H3C 3J7

Editors' Note on Process
In preparing this book, we used generative AI as a writing assistant and in-house editor — primarily to support the revision of connective elements such as the introduction, conclusion, and transitions between sections, as well as for proofing. This involved iterative exchanges to clarify formulations, improve flow, and ensure coherence across the manuscript. These interactions were grounded in extensive notes, drafts, and professional experience. The tool did not generate the ideas or arguments presented in this book; it assisted in refining their expression and organization. All content, interpretations, structural choices, and final formulations were reviewed, revised, and approved by us. We assume full responsibility for the content.

Legal deposit, 2026
- Library and Archives Canada
- Bibliothèques et Archives nationales du Québec

Institutional deposit, 2026
- Bibliothèques de l'Université de Montréal

ISBN (English, PDF): 978-1-0692266-2-4
DOI: https://doi.org/10.71781/34563 | Permalink: https://hdl.handle.net/1866/44364

ISBN (French, PDF): 978-1-0692266-3-1 | Permalink: https://hdl.handle.net/1866/44553
ISBN (Portuguese, PDF): 978-1-0692266-4-8 | Permalink: https://hdl.handle.net/1866/44554

Recommended citation:
Williams-Jones B, Abtroun SN, Marsan C, editors. *Navigating Conflicts of Interest in Academia*. Montréal: Conflict-of-Interest Research Group; 2026. https://doi.org/10.71781/34563

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Many of the publications in this book were supported by grants to Bryn Williams-Jones from the Fonds de recherche du Québec — Société et culture (FRQ-SC), the Ethics Office of the Canadian Institutes of Health Research (CIHR), and the Office of the Vice-President, Human Resources and Planning, Université de Montréal.

Introduction

The contemporary university — both the institution and its researchers — is increasingly expected to forge financial links and/or collaborations with private and public sector partners, entities that may sometimes have divergent interests from those of the university and its members (1,2). While far from being a new phenomenon (3), the development of such financial and other interests and links to the university have taken on a new importance over the past few decades.

As such, there is also increasing attention from faculty and policy makers to the potential for problematic conflicts of interest (COI) in the academy — that is, "situation[s] in which a person has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties as, say, a public official, an employee, or a professional" (4, p.68). In particular, the focus has been on the challenges that COI pose for academic objectivity, impartiality and credibility of judgments (5). In response to the risks posed by unmanaged COI, beginning in the 1990s, North American universities started implementing formal policies to address COI, with many institutions updating their policies to better respond to a changing university environment. The reasonable concern is that without adequate policy or regulatory mechanisms, serious COI — whether real, real, apparent, or potential — will result in the loss of public trust and undermine the privileged social status of universities and their members.

The study of COI in professional and governance settings is not new. Yet, the ethics and policy literatures have, for the most part, focused on the problem of financial COI, for example, in the context of clinical research and associated policy responses by medical schools and professional associations (6,7). By contrast, there has been much less attention paid to other sources of COI in the university, such as student-professor relationships or the peer review process; a notable exception is the work of Davis and Stark (8,9). And for our purposes, there has been relatively little discussion or analysis of what might constitute appropriate policy or procedural responses in the broader university setting, beyond the walls of the medical school or bioscience departments.

Similar to studies in the United States (7), research on the governance of COI at Canadian universities has shown that the development and implementation of specific policies varies enormously. Regulations can range from very general statements of principle to brief discussions of COI in other documents (e.g., research ethics or academic integrity guidelines), to focused COI policies for academic and/or non-academic staff, researchers and students (10). Of the more focused or central COI policies, these arguably are *legalistic* or *inspirational* in form. That is, the policies are written either as legal documents with lists of rules (often prohibitions) to be followed by staff, or as principle-based documents designed to encourage and guide ethical behaviour (11).

An analysis of university COI policies, however, does not tell the full story — it is also critical to look at their operationalization and impact on institutional culture. All too often, unfortunately, COI policies and procedures remain obscure administrative documents, little known by the community who they are supposed to serve. In large part this is due to neglect by university administrations to invest in regularly educating members of the institution about what constitutes COI, why it is a problem if left unmanaged, and how to identify and deal with problematic situations. Further, there may be a lack of understanding that institutional culture change takes significant time and energy and so requires sustained

investment in training and continual oversight. Because the means to effect these changes are costly, they are frequently neglected.

In 2006, the Conflict-of-Interest Research Group (COIRG) was created at the Université de Montréal. Through the work of the lead researcher, Bryn Williams-Jones, and his students, the COIRG participated in the analysis of the university's regulations on the management of COI (2007-2008). This was followed by a series of studies on 1) COI management policies in Canadian universities (2009-2012), 2) the transparency of COI policies used by medical journal publishers, 3) COI management in university research ethics boards (2009-2013), and culminated in 4) the creation of a model COI policy for the University and the development of training tools for the identification, assessment and management of COI. These studies were funded by the University (2012-2013), the Fonds de recherche du Québéc — Société et culture (FRQ-SC; 2007-2012) and the Canadian Institutes of Health Research (CIHR; 2007-2012). This program of research on COI management and training continued over the next decade, resulting in further policy analyses, as well as the production of analytic frameworks and decision tools to help inform members of the university community and contribute to shaping behaviour.

The idea for this book was born of a threefold conviction. First, that reflection on COI deserves continued attention in the light of contemporary and ongoing transformations in the academic world. Second, that this reflection should involve a plurality of perspectives in a diversity of academic contexts in which COI arise. And third, that the research findings of the COIRG were innovative and remain relevant today, both in terms of mapping the nature of COI situations and proposing how these can be analyzed and managed.

Between 2015 and 2025, research integrity and research ethics policies continued to evolve, reflecting a shift towards more transparent governance with a strong focus on managing COI. This evolution includes a more encompassing definition of conflicts that recognizes both financial and non-financial interests, the distinction between real, apparent, or potential COI, and the risks associated with institutional COI. Disclosure practices have become more structured and standardized, with increased transparency required across all stages of research. Academic institutions and government agencies are increasingly implementing proactive COI management strategies; national research funding agencies in Canada, the US and Europe have introduced stricter regulations; and international harmonization efforts led UNESCO, WAME, COPE and ICMJE have aligned publication ethics policies with global standards of responsible research. Research integrity is now a field of study and practice, bringing together members of the international academic community at events like the annual WCRI to present the state of knowledge and propose declarations of principles; and responsible research and integrity training and are now commonly embedded in academic and professional development. Yet, new vulnerabilities continue to emerge, particularly in areas like AI and big data, where enormous investment by public and private sectors have created complex partnerships and relations that highlight the need for both ongoing vigilance and adaptation of existing COI management practices.

We have deliberately chosen not to synthesize or unify the various arguments proposed in the different papers of this collection into a single approach or framework. Even when there are cross-cutting themes, there are also important tensions that reflect the very diversity of contexts in which COI occur in the academic world. Running through the collection are three major tensions, between: 1) *individual and institution* — COI are not simply individual faults, they are often the product of systemic issues, so responsibility is not only individual but

shared, and structural; 2) *transparency and trust* — COI declarations are an essential starting point but often perceived as a sufficient control measure; instead, transparency needs to be seen as a means for preserving or restoring trust between colleagues, institutions, and with the public; and 3) *ethics and regulation* — COI policy and procedures are necessary for the identification and management of situations, but these cannot replace ethical approaches, anchored in awareness and dialogue, that contextualise COI situations.

To give a coherence to the collection, the book is structured in three parts that reflect different areas of academic life: 1) *Professors and Students*, 2) *Research and Publication*, and 3) *Institutional Policies*. Parts 1 and 2 start with a series of case studies to better situate different COI situations, followed by articles with both conceptual and applied orientations; Part 3 concludes with a set of texts analysing Canadian and US university COI policies, and a model university COI policy that would be both functional and inspirational, and so useful for helping create an ethical culture of COI management.

Bringing together the results of more than a decade of research on COI — most of previously published, but with the addition of some unpublished manuscripts — each paper links to the original publication and all references are provided with hyperlinks to the source, where available. The three parts of the book each start with a mini-table of contents with clickable cross-references to facilitate movement between the different texts.

This collection provides practical resources for members of the university community (primarily university professors and senior managers), to help think through the identification, evaluation and management of COI. It is also an invitation to debate, to learn, and to reflect on how COI situations can be best addressed, because they are an inevitable fact of academic life. The hope is that this collection will support university stakeholders in better understanding the nature of COI in research and academia, so that they can implement the necessary tools, policies and practices to manage these situations, wherever they arise.

Bryn Williams-Jones, Sihem Neila Abtroun & Charles Marsan

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Beyond a pejorative understanding of conflict of interest

Bryn Williams-Jones

Original version: Williams-Jones B. Beyond a pejorative understanding of conflict of interest. American Journal of Bioethics. 2011;11(1):1-2.

In seeking to clarify the concept of conflict of interest (COI) in debates about physician-industry relationships, Howard Brody (1) highlights the extent to which the problem turns on a common pejorative understanding of COI. Whether it is the academic or public policy "pharmapolgists" or "pharmascolds" talking about COI, there is often a straightforward and overly simplistic correlation made: that is, a conflict of interest — by definition — leads to fraudulent or corrupt behaviour. The same type of reasoning is commonly found in discussions about COI outside the health sciences, most notably in news stories about the awarding of government contracts or the behaviour of corporate executives (see the businessethicsblog.com for discussion of some examples). The problem is that in focusing on dramatic failures to manage COI (e.g., around Vioxx), there is a tendency to strongly associate COI with extreme forms of financial and even criminal misconduct, leaving the public, policymakers, academics, and professionals with a skewed and limited understanding of the concept. The implication is that the *only* interests at stake are financial so there is no room to consider the influence of nonfinancial personal (e.g., career advancement) or institutional (e.g., reputation) interests. Those people who find themselves in a COI must be *bad* or *unethical*; it is not possible to reflect on the circumstances or institutional structures that might have contributed to the conflict, or perhaps even made it inevitable. This conception of COI is so value-laden and pejorative that it gets used as a trump card — "Stop, there's a conflict of interest!" — and all conversation or debate about the interests at stake or how to manage any conflicts ceases instantly. We are left with prejudicial assumptions of the form "that person is bad (but not me)" and inadequate judgments such as "I've been transparent so there's no more COI" (2). As a result, individuals may be likely to hide their COI (if they even recognize it), scared of the consequences that disclosure could bring to their career and reputation, or they may try, often unsuccessfully, to manage alone their COI. Open discussion is simply not an option.

Brody's call for more clarity in the use of the concept of COI is important and should, I suggest, be an opportunity for those of us in the bioethics community to take a closer look at the issue. Financial COIs are clearly a significant challenge in medicine and the health sciences (although they are not exclusive to these domains), and something that has rightly received enormous academic and public policy attention (3,4). It is essential to have in place policies to help identify and mitigate those financial interests that put at risk the confidence of colleagues, students, and the public in health sciences and academic research. But financial interests are not the only source of conflicts, even if they are the most "visible" and discussed; personal or institutional interests may also lead to COI, situations made all the more challenging by the fact that such interests are often completely ignored.

As I've commented in my blog and elsewhere (5), COIs are not inherently unethical; sometimes professional and institutional arrangements make COI likely, even inevitable. For example, as a professor I both evaluate (e.g., grade) my graduate students and promote them through letters of recommendation (for scholarships, positions), and I arguably have an

interest (e.g., building my academic curriculum vitae [CV], promotion) in seeing my students succeed in their studies and future careers. These responsibilities and nonfinancial interests could well bias my judgment (6). But they are also often unavoidable (who better to write letters for students than their supervisor?), so we must reflect on the associated risks or harms of such COI, and then compare these with the benefits and harms of various approaches to managing them (transparency? self-critique or group critique? removal from decision making?). What matters, ethically speaking, is that individuals and institutions have at their disposal effective tools to help them deal appropriately with COIs when they arise (7). In practice, however, such tools for identifying and managing COI may be all too limited in terms of their usefulness.

In the academic community, a primary source of guidance comes in the form of national, regional, and institutional policies, sometimes as specific documents (e.g., journal or institutional COI policies) but also often under the heading of research integrity and research ethics guidelines. My study of formal university COI policies found that these documents were often too narrow (focused on financial COI) and/or legalistic and generally hard to read (8,9). When these policies were well written, they were often neither widely known within the institution nor combined with procedures to help people actually understand and manage the range of interests that might lead to COI. Institutional policies seem more often aimed at protecting the institution from legal liability than at helping researchers understand and manage COI.

As with other ethically complex problems, good policy documents can provide only a partial solution. Other mechanisms, such as discussions about a university's norms and values (10), will be important means of fostering an ethical culture of research and academic practice among students, researchers, and administrators. But as those of us who have been involved with teaching ethics or participated in research ethics review can attest, building such a culture of ethics in academia (and clinical practice) is an uphill battle, and it will be no less challenging with regard to COI. The latter concept is still widely associated with "bad people" or those who work in the biosciences and take "money from Big Pharma," so getting academics or health professionals to recognize that they too can find themselves in COI will be difficult. That being said, I think such a task is possible, but it means going beyond public forums and spending the time and money to organize regular, formal ethics training initiatives (e.g., online courses as some universities have started offering, annual workshops, or seminars in research methods courses) that can help individuals and institutions better identify COIs when they arise, understand their consequences, and learn to manage them when they cannot be avoided.

The crucial point to remember is that academics and health professionals often have a very limited understanding of what COI is, what is ethically problematic, and how it should be managed. The concept of COI needs greater clarity in public and academic discussions, as Howard Brody has noted in his article, if debates about it are to be constructive. But our understanding of the concept also needs to be transformed to 1) remove its pejorative connotations ("COI is Bad!"), and 2) expand its scope to include nonfinancial personal and institutional interests, so that 3) people come to recognize that COI is something that we often have to *live with* and *manage*.

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Part 1. Professors and Students

Part 1 explores the pervasive and multifaceted nature of conflicts of interest (COI) in professor-student relationships within academia. A series of detailed case studies and analytic articles illustrate how COI arise not only from financial incentives but also from interpersonal dynamics, institutional roles, and structural pressures. Examples include professors assigning their own textbooks, writing reference letters, selecting thesis juries, and supervising students in research labs — each scenario revealing ethical tensions between personal interests and professional responsibilities. These texts show that COI are not inherently unethical. They are often unavoidable in academic life, so the challenge then is in identifying these situations so that they can be managed appropriately. As such, institutions should move away from often rigid, punitive policies, to implementing more nuanced, educational approaches to COI management.

Key strategies include transparency, self-awareness, collegial dialogue, and risk assessment approaches that enable proportional responses. The concept of "critical distance" is introduced, in the context of thesis jury composition, as an approach to balancing expertise with impartiality when everyone is to some degree interested. Institutional recommendations include developing clear and nuanced procedures, fostering a culture of ethical reflection, and supporting faculty with training and practical decision tools. For professors, they are encouraged to have open discussions about COI with students and colleagues, and to see these situations not as something to be ashamed of but instead as valuable learning opportunities.

In reframing COI as a structural feature of academic life, it becomes something that can be managed with integrity and care – and that means taking collective responsibility for building ethical academic environments that support fairness, trust, and excellence.

Case Studies

- University textbooks: an acceptable conflict of interest?
- Reference letters and conflict of interest: a professor's dilemma
- Choosing thesis juries: the costs of taking a strict line on conflicts of interest

Articles

- Supervisor-student relations: examining the spectrum of conflicts of interest in bioscience laboratories
- Professors and the management of unavoidable conflicts of interest: don't always need the heavy artillery of policy
- A procedure for managing conflict of interest when forming thesis juries

Case Studies

University textbooks: an acceptable conflict of interest?

Bryn Williams-Jones

Original version: Williams-Jones B. University textbooks: an acceptable conflict of interest? BioéthiqueOnline. 2012;1(9).

Summary

This case study examines the conflicts of interest that arise when university professors use as required course readings their own textbooks.

Acknowledgements

I would like to thank Chris MacDonald for initially bringing this issue to my attention, Jean-Christophe Bélisle Pipon for his helpful comments on the manuscript, and the reviewers Christopher McDougall and Maude Laliberté for their thorough and constructive evaluations. Many of the ideas presented in this case study benefited from ongoing critique and discussion with the Conflict-of-Interest Research Group at the Université de Montréal. This research was supported by grants from the Fonds de recherche du Québec — Société et culture (FRQ-SC), and the Ethics Office of Canadian Institutes of Health Research (CIHR).

This case study was inspired by a story by Todd Pettigrew in Macleans magazine, entitled Conflict of Interest and Textbooks.

The Case

College and University professors in North America have substantial liberty in how and what they teach in their undergraduate and graduate courses, both in terms of syllabus design and assigned readings. Professor Davies, as many of his colleagues, teaches both undergraduate and graduate courses, and quite appropriately uses different teaching materials and pedagogical approaches depending on the type of course and the number and level of students enrolled. In his graduate courses, which are invariably small group seminars of 10-15 students, Professor Davies uses a Socratic style of teaching that is entirely question and discussion driven (no lectures), and based on 3-4 articles drawn from the current academic literature. But for his first-year undergraduate course, which typically counts between 80 and 120 students, he prefers a standard though interactive lecture style with PowerPoint presentations. He strives to regularly pose questions to his undergraduate audience to engage them in discussion (a challenge in a big class!), uses small break-out groups for brainstorming and group presentations, and has introduced innovative online tools and resources (a course blog, chat forum and additional reading materials). Overall, Professor Davies is happy with his class performance and regularly receives excellent student evaluations.

However, Professor Davies has been struggling for a few years to find the right reading materials for his undergraduate course; the academic articles that he would give to his graduate students are too advanced, and the course texts that he's used in the past have either been too general and/or too restrictive in the material covered, and so he has regularly supplemented these texts with additional readings, both from the academic literature (when they were sufficiently accessible to his undergraduate audience) and from his own teaching notes. Another problem with the course textbooks is that he has had complaints from students about their cost, which is often upwards of $100, a potentially prohibitive

cumulative expense for some fulltime students when each of their ten courses per academic year requires a textbook. This problem is exacerbated when professors only use a few chapters or parts of a textbook or require a new edition of the text every year or two (thereby eliminating possible resale of used textbooks).

Professor Davies teaches his course every year, and he has been frustrated with his selection of readings. He could hand out a photocopied course package of articles, but that's "So 20th Century!", and in practice, course packages still require regular updating. Instead, Professor Davies has decided that the best solution would be to write his own textbook. While his course content is diverse, it maps well onto developments in his field, and he knows quite a few colleagues at other universities who would be interested in such a textbook. Through a colleague with contacts at *Big Name Publisher*, Professor Davies secured his very first book contract. Building primarily on his own extremely detailed teaching notes, but also with some select "classic" articles integrated into the book, Professor Davies aimed to stay on the cutting edge of pedagogical innovation, and so wrote the book in such a way that the text linked directly to his PowerPoint presentations (which are included with the textbook) and to his course website where there are additional resources, study questions, etc. In the hardcopy version the links are in the text, but knowing the predilection of this current generation of students, Professor Davies ensured that an eBook was also published so that students more comfortable with laptops and tablet computers than with traditional books would benefit (e.g., easier to follow in class, no need for paper handouts or lugging a heavy textbook).

Delighted with and proud of the final product, in his first class of the term Professor Davies explains his syllabus, teaching philosophy, and the use of and thus need to purchase the required course textbook that he has written. He explains to his new class that in keeping with previous students' concerns about pricing, he negotiated hard with the publisher and managed to keep the price of the hardcopy at $70, and $50 for the eBook. He strongly recommends the eBook because of its interactivity and ease of use, and the eBook has an additional advantage in that students get the following version (with all the upgrades) for a fraction of the initial purchase price. He is surprised when a young student in the front asks "Professor Davies, I agree that the course textbook appears to be an excellent product — I've just downloaded the eBook through my tablet — but why didn't you go Open Source instead of requiring us to pay to purchase?" And to this, another and older looking student adds "Sir, by requiring us to purchase a book that you wrote — and not another textbook — you will presumably receive royalties. Does that not place you in a financial conflict of interest? And by the way, how much money do you receive per book, and for our course?"

Caught off-guard by these questions, Professor Davies, quick on his feet, explains that in answer to the first question, he went with *Big Name Publisher* because they offered to do all the formatting and provide regular support for annual updates and web development; given his other research and teaching commitments, he could simply not do this formatting and updating himself as would be required with the Open Source model. Professor Davies goes on to explain, in response to the second question, that to his knowledge "standard" royalties vary depending on the publisher, with between 10-15% for hardcopy text sales, and 25-50% for eBooks because of the lower production costs. The royalty agreement with *Big Name Publisher* specifies 15% per hardcopy text and 30% per eBook sold, which would amount to between $1050 and $1500 for a class of 100 students. Pointing out that that this falls rather short of a get rich quick scheme, Professor Davies nonetheless acknowledges the conflict of interest. Recognising a teaching opportunity when it presents itself, he decides to capitalise on the expertise in his class and so asks the second student "Clearly you have some knowledge about conflicts of interest: could you please explain to the class what this is, why

it's problematic in our case and more generally, and what you suggest might be a reasonable solution?"

Questions to consider

1. In a class of 100 students, Professor Davies' financial interest is relatively low.
    - Would the financial interest be different if the course were more popular, say 500 students, and given twice a year?
    - Would an increase in the royalty rate to 50% for eBooks change the perception of the risk or magnitude of the conflict of interest (COI)?
    - Would the use of the textbook by colleagues at other universities, and thus increased royalties, make more problematic the COI?
2. A potential harm of the financial COI is bias or perception of bias in the choice of appropriate textbooks (e.g., a reduced range of viewpoints or topics studied). Yet, in this case, there were few or no other appropriate texts from which to choose.
    - Should Professor Davies' financial interest raise questions about the appropriateness of his choice to write his own book, instead of using an existing (even if less appropriate) textbook?
    - Would this perception change if there were other equally good textbooks to choose from?
3. A solution to eliminate this financial COI would be the prohibition of professors from using as required readings in their own courses textbooks which they have written.
    - Would this restriction on academic freedom be justified given the risk to the professor's and the institution's credibility and integrity?
    - Would placing confidence in a professor's ability to choose the most appropriate material not be sufficient?
    - Should Professor Davies be prohibited from publicizing the textbook to his colleagues at other institutions?
4. Professor Davies' response, that is disclosure to and discussion of the COI with the class, proved to be a stimulating learning opportunity.
    - What innovative solutions might Professor Davies and his class develop to mitigate the financial interest?
    - Would giving up on the financial interest be the best solution? What about giving up only the royalties gained from his classes, and not those derived from external sales?
5. Should Professor Davies not simply avoid all the trouble by going Open Source and producing his own free eBook, even if the final result would be less polished than with *Big Name Publisher*?
    - Would this be fair for students who would prefer a hardcopy?

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Reference letters and conflict of interest: a professor's dilemma

Bryn Williams-Jones

Original version: Williams-Jones B. Reference letters and conflict of interest: a professor's dilemma. BioéthiqueOnline. 2012;1(10).

Summary

This case study examines some of the challenges, and in particular conflicts of interest, that professors face in writing letters of reference for their students.

Acknowledgements

I would like to thank Ghislaine Mathieu for her helpful comments and suggestions on this manuscript, and the reviewers Maude Laliberté and Renaud Boulanger for their thorough and constructive evaluations. Many of the ideas presented in this case study benefited from ongoing critique and discussion with the Conflict-of-Interest Research Group at the Université de Montréal. This research was supported by grants from the Fonds de recherche du Québec — Société et culture (FRQ-SC), and the Ethics Office of Canadian Institutes of Health Research (CIHR)

Background

University professors are regularly solicited to write reference letters for their students, whether for admission into academic programs, for scholarship applications or for jobs. Reference letters are a time-consuming but essential responsibility for professors; and such letters can play a very important role in a student's success. Writing a first letter of reference for a student may take between 30 and 90 minutes, depending on the intended purpose, and whether the professor has sufficient knowledge about the student's capacities and academic track record (e.g., through experience in class, supervision, an up-to-date *curriculum vitae* (CV)). Subsequent letters for the same individual often take much less time but nonetheless require updating as the student progresses in their academic career.

Letter writing can lead to a variety of potentially problematic conflicts of interest (COI) for professors. First, professors have an interest in the success of their own students, because it reflects well on the professor's own career progress (e.g., contract renewal or tenure). But professors are also busy with other academic responsibilities and so might be tempted to "cut corners" in order to save time; it is not uncommon to hear of professors asking their graduate students to write "drafts" of the letters, which the professor then revises and signs. In North America, many have noted a veritable arms race in the writing of effusive, multipage reference letters that tout the excellence of every student; it is at the point now that extravagant letters have become the norm (1). This is in stark contrast to the style of letters written at many European universities that may constitute little more than a cold and descriptive paragraph. The result is that North American reviewers (e.g., for scholarships) may look at a *lack* of effusive language as a sign that candidates are less strong than they might otherwise appear. In an attempt to mitigate the inherent favourable bias in letters of reference, some institutions (departments or funding agencies) have moved towards requesting numerical or grade-based evaluations instead of written letters of reference. However, these are arguably no less subjective than the traditional written letters (2), and will likely vary widely depending on departmental or institutional cultural. In summary, the

writing of reference letters can lead to a variety of COI that can raise concerns about professors' abilities to meet their professional responsibilities towards their students and colleagues.

The Case

Professor Dubois is known in her department for being an excellent mentor to her undergraduate and graduate students. She often spends significant time with each student over the course of their academic programmes, helping them identify and capitalise upon opportunities, and encouraging them to challenge their own limits in order to excel in their chosen areas of research and scholarship. Professor Dubois prides herself on her honesty and candour in her relations with her students, so while she encourages all her students, she also makes it clear when she perceives limits or weaknesses in their work, effort or capacities. Over the last few years, Professor Dubois has supervised more than a dozen graduate students as well as some undergraduate projects, and has been happy to see a good number of these students succeed in scholarship competitions. She has found this both personally gratifying and, indirectly, also financially interesting. That is, for those students who succeed at obtaining major scholarships, she is no longer under pressure to provide salary support through her own research grants. Also, students with scholarships tend to graduate more quickly, and this reflects positively on Professor Dubois' own CV and tenure evaluation.

Writing reference letters, often considered an onerous task by her colleagues, is actually something that Professor Dubois enjoys because it enables her to share her enthusiasm for and translate her knowledge about her students; over the years, she has learned to write excellent and convincing letters of reference, something that she has had confirmed both by successful students and by colleagues who have read her letters during competitions. Nonetheless, Professor Dubois also recognises the problematic nature of reference letters. While her students are competing for scholarships (sometimes from the same funding organization), Professor Dubois is competing with other colleagues who are also promoting their students, with the result that there may be a non- negligible interest for professors to overemphasise or even exaggerate the strengths of their own students. Striving to be fair and honest, she nonetheless writes the strongest possible letters for her students, even when she is not fully confident of the student's capabilities, or when she does not know the student very well (usually for undergraduate students). Professor Dubois feels that all students deserve a chance to compete for scholarships because "they can't win if they don't try" and one never knows what the competition is like. But this philosophy has also led to some uncomfortable situations that have made Professor Dubois question the appropriateness of her stance on writing letters of reference.

Competing Professional Interests

Alex, a graduate student who had taken one of Professor Dubois' courses, has asked for a letter of reference, because he needs a second letter alongside one already obtained from his supervisor, Professor Brennan. Though normally this would not have posed a problem, Professor Brennan is a colleague with whom Professor Dubois' team is in direct competition for grants and first publication of discoveries, a situation that has created some tension in their professional relationship. Professor Dubois thus decided to refuse to write Alex a letter on the grounds that she could not be fully impartial and write a strong letter of reference.

Equality or Merit?

Letter writing has proven particularly challenging for Professor Dubois when she has multiple students in the same competition for which there are only very few scholarships. In such

cases, it can be very hard to write each student who asks a strong letter, and so Professor Dubois is unsure how to fairly manage this situation. She has considered restricting her letter writing to only her own students, although this would clearly have negative implications for other undergraduate or graduate students in her department who do not (yet) have supervisors, and who also need letters in order to apply for scholarships.

Objectivity

Even more challenging for Professor Dubois is the situation where she is on the jury for internal (e.g., Departmental or research centre) scholarship competitions, and is forced to rank her own students objectively against those of her colleagues. In these cases, she has tried to be both equitable and transparent but is nonetheless concerned about her ability to be impartial in her evaluations of her own and her colleagues' students.

Questions to consider

1. Professor Dubois' attention to mentoring her students, and her real interest in seeing them succeed, has led her to question how objective she can really be in the letters that she writes.
    - Will her tendency to write very strong letters for all students undermine her credibility with external reviewers (either in her university or in national competitions)?
    - And does this tendency mean that Professor Dubois is being unfair towards more promising students, who are in a sense brought down to the level of less competitive students, because all receive glowing letters of reference?

2. Her students' success in obtaining scholarships and career advancement also reflects well on Professor Dubois' own academic reputation.
    - Does this create a problematic COI with regards to favouring her own students over those of her colleagues?
    - What about the financial interest of not having to support those students who are working on her research projects because they succeeded in obtaining scholarships?

3. Professor Dubois clearly recognises the challenge of writing letters for multiple students for the same competition.
    - Should she accept to write all letters, making each as strong as possible, or only write a letter for the "first student through the door"?
    - Should she limit her support to her own graduate students, for whom she has direct responsibility?
    - Should she write letters for only those students who, in her judgment, are most likely to succeed in the competition?

4. Significant time and effort is involved in writing letters of reference for students.
    - Should Professor Dubois only write letters for those who she thinks are the best and for whom she can write excellent letters?
    - Or should she "be nice" and not discourage students, and so accept to write letters even for students who she does not think are sufficiently competitive?

5. In the case of Professor Brennan's student, Professor Dubois was in a challenging COI because she was being asked to help the student of a competitor. By refusing to write the letter of reference, Professor Dubois avoided being biased in her letter. But this

also meant that the student would have to find another referee to write a strong letter, which could be difficult.

- Could Professor Dubois' refusal to write the letter be perceived as a COI, i.e., intentionally not supporting the student of a colleague/competitor?
- Should she still have tried to write a strong letter of reference? After all, it is not the student's fault that Professors' Dubois and Brennan are in competition.
- What other options could Professor Dubois have deployed to manage the COI?

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Choosing thesis juries: the costs of taking a strict line on conflicts of interest

Bryn Williams-Jones

Original version: Williams-Jones B. Choosing thesis juries: the costs of taking a strict line on conflicts of interest. BioéthiqueOnline. 2012;1(6).

Summary

This case study examines the conflicts of interest (COI) that can arise in the selection of jury members to evaluate a PhD thesis, and the costs (time, personnel, expertise) associated with trying to avoid COI.

Acknowledgements

I would like to thank Charles Dupras and Ghislaine Mathieu for their helpful comments and suggestions on drafts of this manuscript, and the reviewers Maude Laliberté and Christopher McDougall for their thorough and constructive evaluation. Many of the ideas presented in this case study benefited from ongoing critique and discussion with the Conflict-of-Interest Research Group at the Université de Montréal. This research was supported by grants from the Fonds de recherche du Québec — Société et culture (FRQ-SC), and the Ethics Office of Canadian Institutes of Health Research (CIHR).

This case study was inspired by a commentary by Yves Laberge, How external is your external examiner?, in University Affairs, and my own experiences with the constitution of PhD juries.

Background Context

The University is the site of many interesting and challenging conflicts of interest (COI) that go beyond purely financial interests (1). In many cases, these COI result not from individual misbehaviour, but because of institutional realities that create situations where people necessarily and unavoidably have multiple and potentially conflicting interests (2). A case in point is how juries are constituted to evaluate graduate theses, whether for the Masters or PhD. When students submit a Masters or PhD thesis for evaluation, it is common (and sometimes even obligatory) to require impartial examiners of various sorts (e.g., external to the student's home department and/or university) to review the thesis. The goal is to ensure that there is rigorous academic review and that the thesis meets widely shared academic standards. However, in light of expanding interdisciplinary and international collaboration, alongside both the increasing irrelevance of geographical location and the hyper-specialization of research fields, it is possible that the people best placed to review a graduate student's thesis may have also collaborated with the supervisor and/or the student.

Academics have multiple obligations (e.g., teaching, research, conferences, grant writing) that can make organising a thesis jury a complicated and time-consuming process. Colleagues may refuse to participate because they are simply too busy. While there may be a tacit expectation in the academic community and on the part of a professor's institution that they should participate in evaluating theses, being on a thesis jury is nonetheless volunteer work and often given little credit as compared to research activities (grants and publications). So when one considers professors' other responsibilities, it should not be surprising that for some, reviewing theses will not be a priority. As a result, professors may have to call in

favours to get colleagues to review student theses or sit on juries. This is complicated by the fact that there may be little if any funding with which to physically bring in colleagues from out of town to participate in a jury. Although video conferencing can be a useful compromise, it has its own technical, financial and social limitations, particularly with regards to maintaining dynamic interactions. These contextual issues may thus be the source of or instigators for a variety of potentially problematic COI (3).

The Case

Professor Jones has been a professor for six years and just received his tenure. To date, he's graduated half a dozen of his Masters students and is thus quite familiar with the evaluation process in his department. Specifically, and in compliance with a Faculty policy regarding Masters thesis juries, he has to identify four colleagues who are willing to be named as potential jury members — two as President and two as evaluators — and then submit this list to the Dean's office, where someone (usually the Vice-Dean in charge of student affairs), searches Google Scholar to establish whether Professor Jones or his student have published with any of the suggested jury members in the last five years. This policy was implemented in response to some particularly problematic COI situations that had occurred in previous years, and which had brought into question the independence and objectivity of some jury members (e.g., who were friends and close collaborators of the supervisor), and thus the reputation of the Faculty. Other Faculties have adopted different measures and procedures, including leaving the issue to the discretion of individual departments.

The process of constituting MA juries has sometimes proven to be a time consuming and frustrating process, because Professor Jones' colleagues are all very engaged in research and teaching and thus have many other commitments. As Professor Jones has been active in building research collaborations both within and outside his department, there are many colleagues who would be ideal jury members but who cannot participate because of the Faculty's COI provisions. Nonetheless, Professor Jones is an amiable fellow and a good colleague (he regularly accepts to sit on MA juries of his colleagues' students), so he has managed to organise competent (if not ideal) juries to evaluate his students' MA theses, and the results have been invariably positive and rewarding to all involved.

This summer, Professor Jones is hoping to graduate his first PhD student, Jessica Dupuis, who is wrapping up a superb research project that blends a variety of theoretical and conceptual models but applies them to practical, real-world contexts. Jessica already has four of her thesis chapters published in national and international peer-reviewed journals, co-authored with Professor Jones (second author on all the papers), and their colleague Professor Williams (third author on two of the papers) who is a senior professor at another university in the same city. Professors Jones and Williams meet with Jessica to talk through the selection of potential jury members. Jones informs them that according to his Faculty, a PhD jury should normally comprise at least 5 members, and it is up to the supervisor to provide a list of 8 possible candidates for the various positions on the jury, contacted in advance to obtain their approval to be nominated:

1. President (2 names): a voting member, should not be in COI with the student or supervisor;
2. Supervisor (Professor Jones) and co-supervisor if applicable (none, in this case);
3. Internal jury member (2 names): from the University, and should not be in COI with student or supervisor;

4. External jury member (2 names): from outside the University and should not be in COI with the student or supervisor.
5. Dean's representative (2 names): from the University, a non-voting member to ensure good governance of the meeting.

Identifying 8 colleagues who are willing to read a 200-page PhD thesis and participate in an early summer exam is no mean feat; something made all the more challenging by the COI regulations prohibiting involvement of colleagues with whom Professor Jones or Jessica have collaborated. For a start, this obviously rules out any direct involvement on the part of Professor Williams, who while not a co-supervisor on Jessica's thesis, is a close collaborator with Professor Jones and co-author on two of Jessica's articles.

Professor Jones identifies two colleagues who would likely accept to be President, who are interested in Jessica's research subject in general but certainly not experts, although such expertise is not required of them in their role as President. The same is the case for the Dean's representatives, who do not even need to be in the same field of study, nor are required to read the thesis; they are responsible for ensuring that the process is fair, impartial and conducted in a respectful manner. Nonetheless, Jones has colleagues in mind who would be interested in Jessica's research and so likely to agree to participate.

More difficult, however, is the choice of internal and external jury members; Jessica's research is quite specialised, and Professor Jones is part of a small but vibrant research community with whom he regularly collaborates on research grants and publications. Jessica suggests Professor Smith, one of the professors with whom she took two graduate courses (and got A+ grades in both courses). While not a specialist in Jessica's specific subject, Professor Smith taught on and does research in relevant if tangential subject matter; Jones knows this colleague and agrees that she would be a good choice. For the second internal jury member, they have to stretch even further the boundaries of expertise, and Jones suggests Professor Thomas, a colleague in another Department whose research focuses on one of the theoretical aspects of Jessica's projects, but in an entirely different area and with different applications. Professor Thomas is known to be very tough, but fair, and so they decide to "take the risk" of including her as a potential jury member, even though she could raise very challenging conceptual and theoretical critiques to Jessica's thesis.

For the external examiners, Professor Williams suggests a friend and colleague at a university in a nearby city, who is an expert in the subject matter. Professor Renaud is a nice person who will give a fair evaluation but not be overly harsh. Jones and Williams have both been present at and even participated in unpleasant PhD defences, due to the involvement of either non-expert and/or overly critical and even nasty examiners, so they want to ensure that the jury is balanced and fair to Jessica, while still being rigorous. There is another expert in the field, Professor Beaudoin, who would be ideal, but Jones and Williams know her only by reputation and she is in another province. With only a $500 budget available from his Faculty to bring in external jury members, Jones suggests to Williams and Jessica that he offer to fly Professor Beaudoin out for a week at his expense (to be paid off a research grant) should she agree to be named as a potential jury member and eventually be chosen by the Dean's office.

After more than two hours of discussion, Professors Jones and Williams, and PhD student Jessica Dupuis, have agreed upon what they think is a viable list of names for the jury, one with a good balance of expertise and rigor given the limits imposed by their Faculty's COI

regulation. Jones proceeds to start emailing these colleagues to solicit their participation on Jessica's PhD jury, hoping that they will all accept to be named as possible jury members.

Questions to consider

Professor Jones' Faculty policy on the constitution of MA and PhD juries precludes, in the interest of avoiding COI, the naming of jury members who have collaborated with the student or supervisor on a grant or publication in the last five years.

1. Are co-authorship or collaboration on grants the only relevant COI that the Dean's office should be evaluating in the constitution of a jury?
    - Is a Google Scholar search a sufficient detection method?
    - Is the Dean's office best placed to judge COI of jury members?
2. While important, the identification of potential jury Presidents and Dean's representatives appears to be largely unproblematic.
    - Are there particular concerns that Professor Jones or the Dean's office should have in the choice of these jury members?
3. Does the fact that Professor Smith (potential internal jury member) has taught Jessica in two courses and given her A+ grades pose any problem?
4. Should the fact that Professor Thomas (potential internal jury member) is "tough but fair" and could be very difficult on the jury, or that her research is far more theoretical than is the case for Jessica's applied project, be factors worth considering? Do they create COI?
5. Does Professor Renaud's "being a nice person" not pose a problem of objectivity, and even COI? Such personal characteristics are simply undetectable by the Dean's office.
    - Is it fair that a student must rely on their supervisor's competence and behaviour with colleagues to have a "nice" jury?
6. Would Professor Jones' offer to pay the travel expenses of Professor Beaudoin constitute an undue influence? And is this a legitimate expense for a research grant?
    - If the Faculty were unable to pay, would there be other ways to "blind" the source of funds (Professor Jones) or otherwise create distance to mitigate this financial COI?
7. Should the real difficulties that Professor Jones — and certainly other professors in the Faculty — encounters in constituting an impartial PhD jury committee lead to a re-evaluation of the COI policy?
    - Should expertise be a more important criteria for selection than COI? If so, how can one avoid the perception of bias and favouritism?
    - Would the declaration of relevant COI be a potentially useful solution to the problems of finding expert evaluators? If so, in what cases, for what types of COI?
    - What alternative approaches might be considered to the current restrictive Faculty policy and practice?

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Articles

Supervisor-student relations: examining the spectrum of conflicts of interest in bioscience laboratories

Chris MacDonald, Bryn Williams-Jones

Original version: MacDonald C, Williams-Jones B. Supervisor-student relations: examining the spectrum of conflicts of interest in bioscience laboratories. Accountability in Research. 2009;16(2):106-26.

Abstract

Much attention has been given to *financial* conflicts of interest (COI) in bioscience research. Yet to date, surprisingly little attention has focused on other COIs that arise in supervisor-student relations. We examine a spectrum of related situations, ranging from standard graduate supervision through to dual relationships sometimes found in research with commercial potential. We illustrate some of the less-obvious factors that can bias supervisory judgment and situate financial COI along a spectrum of forces that are deserving of recognition. We conclude by providing two sets of recommendations: one for individual supervisors, and the other for institutions and policy-makers.

Acknowledgements

The authors would like to thank Catherine Olivier, Jason Behrmann and Vural Ozdemir for their extremely helpful comments and their insights into the culture of bioscience laboratories; Wayne Norman for helpful comments on a draft; and Elise Smith, Vincent Couture, Ashley Pringle and Aimee Smith for their valuable research assistance. This study was supported by grants from Université de Montréal and the Institute of Genetics of the Canadian Institutes of Health Research.

Introduction

In the biomedical sciences, close interactions between academic and commercial entities are commonplace. Funds from pharmaceutical and biotechnology companies have helped finance major bioscience projects and research centres, graduate students are receiving training in commercial laboratories, and university scientists are translating their intellectual property by patenting and licensing their research or launching start-up companies. Such interactions have received the blessing of universities and local and national governments (1,2). But concerns have also been raised about the ethical challenges posed by university-industry relations, especially with regards to academic liberty and conflict of interest (COI) in the context of dual loyalties (e.g., researcher's duties towards their departments and industry partners) (3,4).

In university contexts, COIs are often seen as being primarily an issue for biomedical researchers. Particular attention has been given to the influence that receiving consultation or patient-recruitment fees, or having shares in biotechnology or pharmaceutical companies supporting clinical trials, can have on medical judgment, patient safety in biomedical research, and the function of medical schools (5,6). Concern extends more generally to the publication of scientific research in peer-reviewed journals, and the need for transparency and declaration of competing interests on the part of researchers and institutions (7-9). Much less well studied, however, is the relationship between university professors or faculty-level

researchers — specifically laboratory directors working in the biosciences — and their students, or the particular case wherein the researcher is also a director or head of a start-up company, and the student is also their employee. In both situations, there is arguably a "dual relationship" that can lead to important conflicts (10); unfortunately, university regulations (including COI policies) are rarely equipped to deal with this particular issue (11,12).

In this paper we examine a spectrum of related situations, ranging from standard, relatively uncomplicated graduate supervision, through to the dual relationships sometimes found in research with clear commercial potential. We argue that ethical challenges across this spectrum include not just conflicts of interest but also conflicts of obligation. Further, we argue that the particularly challenging conflicts that occur with regard to commercial ventures — and about which so much concern has been expressed in the literature (13-15) — are best understood as part of the larger spectrum of challenges that inevitably arise when complex organizational structures are devised to meet complex human interests and needs.

In order to give readers unfamiliar with laboratory environments a better sense of the context we are discussing, we will first sketch the characteristics typical of a university-based research laboratory.

The Laboratory Environment

Academic bioscience laboratories are team-based research and teaching environments, based in fundamental or applied science departments such as biology, biochemistry or medical genetics. A small lab may have 5-10 members, while a big lab could have 12 or more (some as big as 70 members). Labs are hierarchical in organization and are directed by a faculty member (the lab director) who funds the research activities out of research grants. The director supervises research associates (in the bigger labs), post-doctoral fellows ("post-docs"), technicians and graduate students. Post-docs manage their own projects and may occasionally (more commonly in the United States) have an undergraduate student or a technician working with them. Research assistants and/or technicians will work directly under the director or under a research associate. Graduate students will often have undergraduate students to supervise.

In North America, funding for university bioscience research is obtained primarily through peer-reviewed grants from government science councils (e.g., the US National Institutes of Health and National Science Foundation, or the Canadian Institutes of Health Research). Operating funds can also be derived from charitable foundations and industry sources. These resources are used primarily to purchase research equipment and pay salaries. The employees in a lab include technicians, research assistants (graduate students or individuals with graduate degrees), post-docs and research associates. Unless otherwise supported by external scholarships, students and post-doctoral fellows are paid salaries from their lab director's operating funds to conduct research while working to obtain their degrees, i.e., they are quasi-employees but usually without contracts or employment benefits. Graduate students may also be involved in a diversity of more formal employment relations. They may do other work within the university, perhaps as a Teaching Assistant or Exam Invigilator, Alternatively, they may work as contractors or consultants for industry-sponsored research projects, or even as part/full-time employees in spin-off companies. Students sometimes also conduct the research component of their graduate studies within industry laboratories with which their supervisors have ties, whether or not they are also employees of the company.

The members of a lab work to further the director's particular research agenda; the work they do will also contribute to their individual graduate theses (which may constitute focused sub-projects, part of the larger research program), academic presentations and publications. Students work closely with their senior colleagues to learn the practical and theoretical skills necessary to conduct experimental research. In bigger labs, students often will interact more frequently with a senior student or post-doctoral fellow than they will with their lab director, who is their official departmental supervisor and responsible for their academic progression; in smaller labs, the students are more often directly supervised by the lab director.

Laboratories rely on close working relationships: parts of or the whole team will be actively involved in developing and testing ideas, running experiments, and contributing to the production of research results in the form of posters or presentations at national or international meetings, and peer-reviewed publications. In many fields of bioscience, research and publication are highly competitive; a number of labs may be working on the same research question and racing to be the first to present or publish a scientific discovery. Thus, the training and retention of capable graduate students and research staff, as well as the protection of research confidentiality (until publication), will be important issues for a lab director.

Academic bioscience laboratories sometimes make discoveries or develop technologies that have potential commercial value. Patents may be sought in order to license the product to biotechnology or pharmaceutical companies for further development and commercialization, or to be licensed to other laboratories in the case of scientific research tools. On occasion, a discovery or technology may be sufficiently promising that the director considers starting a spin-off company to commercialize the discovery. This decision is not taken lightly or alone; it necessarily involves extensive discussions between the lab director and the university technology transfer office (including lawyers and patent officers), to evaluate the patentability of the discovery, the value of the intellectual property, and the availability of venture capital, among other factors.

Of course, not all academics will have the requisite management skills or entrepreneurial ability to develop and grow a successful spin-off company and become 'merchant scientists.' Most will continue to pursue their basic or applied research in the university environment (16). In other words, despite the political rhetoric about universities becoming entrepreneurial institutions, many bioscientists still have little interest in commercialization or the development of spin-off companies. That being said, they (and their graduate students) may be supported by and work with industry partners, conduct contract research or consult for companies.

The subset of researchers interested in setting up a spin-off company may be attracted by the opportunity for personal gain in terms of academic prestige and financial rewards, as well as by closer ties with other private companies that may eventually help fund other aspects of the lab director's research program. A spin-off company may also be seen as a means of making practical contributions to the advancement of science and the development of new and useful products (especially diagnostic tests and medicines) that will benefit patients and society at large (17). Spin-offs from academic laboratories will often be located at private research labs, which may share space and facilities with the academic lab; alternatively, they may be physically separated and housed nearby or at an off-campus university science park.

Life in a spin-off company imposes demands on the time and freedom of university-based researchers. A university researcher entering that world will have to consider managerial

issues, such as which employees to hire (including not just research staff but also clerical and administrative staff) and how to separate their university research activities from those of the company. (Some universities have explicit policies to guide such activities (11)). In addition, such researchers will often have to become accustomed to spending long hours seeking out venture capital to support their commercial research and planning the production and protection of the company's intellectual property. The researcher/director of a new spin-off will have to closely evaluate their capacity and willingness to take on the full responsibilities of leading the company. As companies, grow, some researchers will choose — often under pressure from investors or the company's board of directors — to hire a manager experienced with biotech spin-offs to take over as the Chief Executive Officer (CEO); the researcher then in turn may become the Chief Scientific Officer (CSO) and focus on charting the scientific direction or priorities for the company, a role more closely fitting their academic training and expertise (18). This can be a difficult decision for the researcher to make, because it involves handing over a significant degree of control of the scientific project to non-scientific experts. At this point, the researcher may shift their focus back to the university environment (while maintaining links with the company and, for example, conducting contract research), or leave the company altogether (although they may retain stocks or stock options in the company).

Having sketched the environment of university and commercial labs, we can now begin our exploration of some of the central ethical challenges raised in graduate student supervision in the biosciences.

Three Kinds of Supervisory Relationships

Supervisory relationships come in many shapes and vary significantly in their form and complexity. We next sketch three very rough categories of supervisory relationships, pointing out the kinds of conflicting obligations and potential COIs that may be found in each. Our aim is to illustrate the range of conflicts that can occur along this spectrum of supervisory relationships.

1. Graduate supervision

The simplest relevant relationship, namely the straightforward supervision of a graduate student by a university professor, is uncomplicated by any commercial interests or relationships. Yet it is important to note that even such straightforward supervisory relationships involve inherent COIs. Supervision requires the exercise of judgment on the part of the supervisor. University and Departmental regulations notwithstanding, supervisors must normally exercise judgment in deciding the type and quantity of work to assign to students, in devising grading schemes, in evaluating student work, and in writing letters of recommendation. Supervisors must also exercise judgment regarding the type and quantity of supervisory activity: the number of hours of contact time granted to a supervisee is a crucial variable. Since students are typically unable (partly because they are unqualified) to judge in a precise way the quality of supervision, supervisory judgment is typically exercised with considerable leeway. This suggests that the supervisory relationship is, at heart, a fiduciary — that is, trust-based — relationship (10).

Further, supervisors always have other obligations and interests that stand in tension with the demands of supervision. To begin with, university professors typically have a range of professional obligations other than graduate supervision. These obligations include teaching courses, engaging in scholarly research, and serving on university committees. Professors may also have obligations rooted in roles they play beyond the walls of the university:

obligations to family, and to their religious or cultural communities, and obligations of citizenship. In addition to competing *obligations*, they also naturally have a range of *interests* that may conflict with supervisory obligations. For example, professors typically have a natural (and reasonable) interest in leisure and hobbies, in career advancement, in making a substantive contribution to their fields, and in having their students succeed in ways that reflect well on them as supervisors.

We see already, then, in simple supervisory relationships, the ingredients of a classic COI. A COI is any situation in which an individual is in a role requiring them to exercise judgment in the service of some other individual or institution, and in which they have some interest that stands to make it harder for them to exercise that judgment objectively. Professors, in their role as graduate supervisors, are expected to exercise judgment in the educating and mentoring of graduate students; *any* interest they may have in anything other than the student's education and training puts the supervisor in a conflict of interest. Of course, many such conflicts are unavoidable, since every professor has multiple interests. All we can expect of professors in supervisory roles is that they do their best to recognize factors that may bias their judgment and do what they can to minimize their effect.

It is worth noting just how hard it is to distinguish cleanly — within the class of things that might bias a graduate supervisor's judgment — between a professor's obligations on the one hand, and their interests on the other. For example, a professor's *interest* in career advancement may inspire him or her to do more than the minimum expected, in terms of the obligation (often written into academic contracts) to engage in scholarly research. And the question of whether to call the act of attending to the needs of one's family a matter of 'obligation' or a matter of 'interest' is a complicated one: some at least will define one's 'interests' broadly enough to include the interests of those that one cares about, and to whom one also doubtless has obligations. Thus, even the simplest of supervisory relationships raise questions of conflict, though hopefully not insurmountable ones.

2. Supervision plus employment of graduate students

We move now to a second, somewhat more complicated scenario, namely one in which a professor supervises a graduate student, while at the same time employing that student as a research assistant in their lab or as a teaching assistant for their courses. Supervisory relationships of this kind retain the complexity manifested by the 'simpler' relationships described in the previous paragraphs. But they also bring additional worries, because such relationships are in fact subject to two different normative regimes, namely one set designed to govern supervisory relationships, and a separate set designed to govern employment relationships.

Following Davis (19) we take the norms governing supervisory relationships to be, like the norms governing relations with students more generally, a combination of two sets of norms governing university professors. One is the set of institutional norms governing 'the academy,' which is in essence the name given to the shared enterprise engaged in by professors, students and university administrators. The other is the set of norms constituting the professional ethics of the professoriate. (A full explanation of the overlap and differences between those two sets of norms is beyond the scope of this paper.)

The relationship between supervisors and graduate students is best characterized as a fiduciary relationship: imbalances of knowledge and power mean that the student must trust that the supervisor will conscientiously provide reasonably high-quality education and mentoring. Though the professor's student (unlike, perhaps, the physician's patient) is not

best thought of as helpless, the inability of the student to assess anything more than the most superficial aspects of the professor's performance of their supervisory duties means that professors must be trusted. In particular, we need to be able to trust that students won't be exploited for their supervisor's gain. Hence, professors must (and generally do) understand themselves to be obligated to be more diligent in tending to the interests of their supervisees than would be the case if their relationship with supervisees were a simple contractual relationship between consenting individuals.

The *objectives* of graduate supervision — the ends towards which the norms governing such relationships provide guidance — are relatively clear. The most obvious goal is to help the student acquire the knowledge and independent research skills suitable to their academic discipline. In the biosciences, supervision also typically involves mentoring aimed at helping prepare the student for the transition into the workplace: depending on the student's goals, this may involve learning a combination of hands-on laboratory procedures and conceptual research skills, as well as professional skills related to disseminating research results through conference presentations and scholarly publications.

All of this, of course, is constrained by the norms of both science and academia. Academic norms require that students be evaluated fairly and objectively. Both scientific and academic norms support the idea that what the supervisor is helping the student to learn is how best to pursue knowledge as an independent scholar. Supervisory ethics, therefore, requires that the supervisor seek what is in the student's best (academic) interests, subject to the limits posed by standards of academic quality and scientific integrity. It is also worth noting that the norms governing supervision of graduate students are largely unwritten and effectively unenforced. University and departmental guidelines may provide a certain amount of guidance, and some students might indeed look up to them for some indication of what their supervisors' obligations are. But the guidance provided by such documents is likely to be very loose, and a supervisor could easily follow their letter without adhering to their spirit.

In this second category of supervisory relationships (i.e., dual supervisory-employment relationships), another set of norms is relevant, namely the set of norms governing employment. The norms governing relations between employers (or managers) and employees are quite different, even within university settings, from those governing the supervision of students. Employment relations are fundamentally contractual: the employee exchanges labour (i.e., the application of physical and/or mental effort to the employer's projects) in return for some form of remuneration (primarily consisting of a wage or salary). Thus, the primary obligation of an employer is to live up to both the letter and the spirit of the employment contract, in pursuit of the production of some external good (some product, service, or in this case scientific discovery). The norms governing employment can easily conflict with the norms governing supervision. The conditions under which a relationship may be terminated provide a good example. A supervisor should, other things being equal, retain a student as supervisee until that student's degree or project is finished[1]; an employer is obligated only to retain an employee until the employment contract runs out, or in the absence of a contract, until the employee's services no longer serve the employer's needs.

We thus see potential for both conflict of interest and conflict of obligations, with the additional complexity of two competing sets of regulatory norms. In a complex relationship,

[1] In some institutions, the supervisor may even have an obligation to see a student through to completion, or abandonment of the degree; in contrast, a student is usually free to change supervisors at their discretion.

a single individual, acting as both employer and supervisor, can have two or more divergent obligations at the same moment.

3. Supervisory-employment relationships and commercial research

We move now to discuss the third type of relationship within our proposed spectrum, namely dual supervisory-employment relationships that take place specifically within university research labs doing work with clear commercial potential.

Such settings are subject to all of the worries associated with the previous two categories but are in addition subject to a further set of worries, including worries closely linked to those that have spurred criticisms of university-industry relationships. Such worries spring, of course, from concerns about the influence of the profit motive. The key worry is that the possibility that research might turn profitable puts professors, who are in supervisory roles over students working in their research labs, in a serious COI. For example, it is possible that the profit motive could affect a professor's supervisory advice. Although we know of no solid empirical evidence, the 'folk hypothesis' is that money is a particularly potent source of bias.[2] In particular, the worry is that a professor with commercial interests might give biased advice on choice of thesis topic: a student might be pushed towards a topic that will contribute to valuable, patentable discoveries (for which the professor is more likely than the student to get credit) rather than a topic that will result in publishable findings that will advance the student's career. Similarly, advice on the timing of graduation might be influenced by their interest in having the student contribute to potentially-profitable research.

It is worth noting that this category — "university labs doing work with commercial potential" — is somewhat amorphous: it may be hard to recognize, from the outside, labs that are doing work with commercial potential. But most if not all biomedical laboratories conduct work that has, at least, commercial potential of some sort, even if their work is not likely to result in the development of a blockbuster pharmaceutical. And to a certain extent, what matters in terms of the issues discussed here is not whether the research being done *has* commercial potential, but whether the professor supervising the lab *believes* that the research has commercial potential. This difficulty in identifying, from the outside, labs that fit this category need not stop us from analysing the relevant problems. It may pose a serious challenge, however, in implementing institutional remedies.

Table 1: Sources of conflict across the spectrum of supervisory relationships

	Type of relationship		
Type of conflict	*Supervision*	*Supervision plus employment*	*Supervision plus employment in commercial context*
Conflict of interest	X	X	X
Conflict of obligations	X	X	X
Conflict of normative frameworks		X	X
Significant financial conflict			X

3.1 CEO (supervisor?) and employee (student?) relations in the spin-off

A particularly challenging case in our third category of relationships is the dual relationships that obtain when a professor becomes head or CSO of a fully commercial research lab at a spin-off company, and one or more graduate students takes on a second role as an employee at that company. It is difficult to locate reliable statistics on how common such dual relationships are, but they do occur. Such situations involve all of the tensions and risks of

[2] In fact, there is some empirical evidence to the contrary (cf. 20).

the three categories outlined above: conflicts of interest (will the professor in such a situation give unbiased advice to her supervisees?), conflicts of obligation (will the professor/entrepreneur prioritize obligations to students, or obligations to family?), conflicting normative regimes (will student-employees be treated as students, or as employees?), and the potentially COI-exacerbating effect of the profit motive. But there is at least one additional set of worries, namely those that spring from the fact that managers in private industry are generally regarded as having fiduciary obligations to owners, investors, and shareholders — fiduciary obligations that stand in tension with the fiduciary obligations that professors owe to their students.

In the private sector, the organization (i.e., a firm) that results from various employment contracts is typically one that is fundamentally hierarchical, and best characterized by the ethico-legal concept of *agency*. In an agency relationship, the agent (here, the employee) is engaged to perform a task that the principal (here, the employer) lacks either the time or the skill to perform. In an agency relationship, the primary obligation of the agent (i.e., employee) is to diligently pursue the legitimate interests of the principal.

Of course, in all but the smallest firms (e.g., start-up biotech companies that may initially consist of only a handful of employees), the agency relationship is actually multi-layered (21): rather than being an agent of the employer, the employee is best seen as an agent of his or her immediate superior, or manager, and the manager is typically an agent in turn for someone at the next step up the organizational hierarchy. With the exception of very small companies (where the manager may also be the owner), managers typically manage on behalf of someone else, whether it be an owner, a small group of investors, or a diverse set of shareholders.

Thus, while the employee is in an agency relationship with the manager and hence owes certain obligations of loyalty, the manager is also typically — and importantly — in an agency relationship with the owners of the company and so is obligated to pursue the owners' legitimate interests. This obligation to the company's owners does imply something about how employees are treated: the owners have obligations to treat employees fairly, and that obligation must be carried out by managers as the owners' agents. But the fact that managers act as agents for owners also implies a *limit* on the obligations owed by managers to employees. So, for example, a manager's obligation to train and mentor an employee are strictly limited to the forms of training and mentoring that are conducive to (and cost-effective in pursuing) the interests of the company. And in carrying out wage negotiations on behalf of owners, managers — while bound by basic rules of honesty and the injunction to bargain in good faith — are generally obligated to pursue the interests of the company's owners, rather than the interests of employees.

It is clear, then, that employment relationships in business firms are governed by norms quite different from those that govern university supervisor-student relationships. The fact that people in managerial positions may be subject to a range of different role-related norms (including potentially conflicting fiduciary obligations) is a central problem of management ethics (21), and many organizations devote considerable energies to establishing policies and informal norms to guide managers through such conflicts. But the conflict becomes perhaps even more critical when a single individual (e.g., the academic entrepreneur) is subject to two different sets of normative constraints with regard to their relationship with a single stakeholder. To summarise, the academic entrepreneur is subject to two different normative regimes: one that requires faithful attention to the educational needs of the student, and one that requires faithful attention to the needs of the owners of the business

and that may put significant limits on their ability to do things that benefit employees. When the student and the employee are one person, the conflict is obvious.

Discussion

The distinction between supervisory relationships and employment relationships is not crisp: after all, many students (across the range of academic disciplines) are paid to work as evaluators in the grading of student assignments (i.e., as teaching assistants), or as lab assistants, research assistants, and so on. But the situation of such student-employees differs in a number of significant ways from the situation of employees in the private sector. Indeed, the differences are more instructive than the similarities. To begin with, in standard employment relationships, the level of remuneration is driven by the market: rare and useful skills are handsomely rewarded, while common and less-useful skills are often paid at a rate at or near the legislated minimum. In academic settings, on the other hand, many student jobs are seen as (among other things) forms of student funding, and the rate of remuneration may in some instances be set implausibly high relative to the value of the work performed; this is particularly the case in the humanities and social sciences (especially when there are also collective agreements for teaching and research assistants).[3]

It is worth looking at the complex situation we are describing from the student-employee's point of view. As we mentioned above, in academic bioscience laboratories, when students do not have their own funding from scholarships, they are invariably paid a salary from the lab director's operating funds. Laboratory research cultures vary significantly, but in general students are expected to spend a minimum of 40 hours per week physically in the lab at their bench conducting experiments; many lab directors will require 70 hours per week or more. Since the director controls the salaries (although granting agencies or departments often set minimum levels of support), they can provide or at least promise bonuses or raises to students. Even a very small hourly raise or a top-up to a scholarship can be used to entice students to finish a project faster, work longer hours (including nights and weekends), and so on. But as students, they lack the benefits that usually come with employment in a company (e.g., vacation time, medical benefits). On the other hand, unlike most regular employees, students may benefit from the prestige of being first (or co-) author on articles, may get funded to travel to and present at national and international conferences, and are often paid to conduct research for which they will receive academic degrees.

The essence of the problem is that the researcher's interests, as manifested in an employment relation with the student (whether this is as lab director or as the head of a spin-off company), may impinge upon their ability to supervise and serve as a mentor for the student in a way that is in the student's best interest. The notion of COI looks quite different in light of these two sets of norms (i.e., the norms surrounding supervision, on one hand, and employment, on the other). In a context that brings these two sets of norms together, COI is a significant threat. In a straight employment relationship with its contractual obligations, the (partial) conflict between the interests of employers and employees is so blatant that it often is not even *called* COI.

It is worth enumerating some of ways in which the range of influences on supervisors' judgment can manifest themselves. Biasing influences on the supervisor-student relationship might show up as:

[3] Levels of remuneration for student work vary enormously across universities and disciplines. But for at least some work — such as grading multiple-choice tests, or photocopying — students are almost always paid significantly more than the wage (probably near the legal minimum wage) that such work would demand outside of a university.

- Reduced quality and quantity of student advising;
- Biased thesis advice (e.g., regarding whether to continue the project or stop and join the company);
- Biased advice regarding timing of student-led publication (e.g., delaying submission for publication in order to protect commercially valuable discoveries[4]);
- Moves to delay graduation to keep talent around (rumoured to be common in academic labs);
- Biased advice on choice of research topics (commercial vs. interest-driven);
- Biased career advice (e.g., whether to pursue a post-doctoral position and an academic career path, or to join the company).

With regard to each of these issues, supervisors face a conflict of interest: their interests as academic lab directors, and as researchers with commercial partners, threaten to influence the advice they give to their supervisees. This is not to say, however, that all supervisors, or those who become company directors and who employ their students in biotech start-ups, necessarily create or encounter unmanageable COIs. Our point is that the supervisor-student relationship in bioscience labs is inherently complex, a mix of often conflicting responsibilities and loyalties which is further exacerbated when the supervisor becomes a 'merchant scientist' and the student an employee of the company.

It is worth emphasizing that the simple fact of being in a COI does not imply that one has done something unethical — the issue is how to handle the situation (22,23). The standard advice is roughly to 1) avoid COIs when possible; 2) disclose the interest to all concerned; and 3) remove oneself from sensitive decisions where feasible. Sometimes 1 and 3 are impossible so 2 (transparency) becomes crucial. But this standard advice may be insufficient. Some guidance can come from ethics (including COI) policies and guidelines, but these vary enormously between universities, are sometimes poorly written and poorly disseminated (24,25) and often do not specifically address supervisor-student relations (11).

Recommendations

In this paper, we have attempted to illustrate the wide range of influences that can impinge upon the appropriate exercise of supervisory judgment in graduate educational settings, and in particular in bioscience laboratories. Our goals here have been twofold. On one hand, we have sought to shine a light on some of the less-obvious (or less-frequently-acknowledged) factors that stand to bias supervisory judgment. On the other hand, in so doing, we have sought to situate *financial* conflicts of interest along a spectrum of forces — some relatively benign, some malignant; some avoidable, some unavoidable — all of which are deserving of recognition and analysis. Though our main goal here has been descriptive and analytic, we see our analysis as pointing to two rough sets of recommendations: one aimed at individual supervisors, and the other aimed at institutions and institutional policy-makers.

Advice for Individual Supervisors

There are limits to how much can be accomplished by focusing on individual behaviour, motives, and integrity. As argued at length by Norman and MacDonald (26), it is becoming increasingly clear that conflict of interest (and the related problems discussed above) is best thought of as a specifically institutional problem: we generally worry about COI not (merely)

[4] Students are often involved in the patenting process, including making patentable discoveries. Some universities in Canada have provisions in their thesis submission guidelines that allow for a student to delay (e.g., by one year) the publication of their thesis in the national library system, in order to protect potential IP or important, publishable information that might be stolen by a competitor.

because it affects individuals (e.g., students) but because it jeopardizes the mission of entire institutions — be they professions, corporations, charities or universities — and jeopardizes the public's faith in them. Thinking even more broadly, COI in bioscience labs can undermine science itself by jeopardizing the mentoring relationships upon which science depends (27). Such being the case, situations in which individual supervisory judgment seems liable to be biased by inappropriate forces are not best dealt with through appeals to individuals to behave appropriately. The reputations of institutions can be damaged by COI, or the appearance of COI, "even when the individual at the centre of the perceived conflict is in fact of unflinching integrity" and has acted entirely appropriately (22). Nonetheless, the behaviour of individual supervisors does have a very direct effect on the lives of supervisees, so a few words of advice are appropriate. We offer the following four suggestions:

1. Supervisors should recognize and guard against the full range of factors that might bias the teaching, advising, and mentoring of their students. The fact that institutional policies may focus on financial conflicts of interest does not excuse turning a blind eye to other, perhaps equally biasing, factors.

2. Supervisors should go beyond a vague commitment to "guard against" COI. As educators, they know that "trying harder" is a poor plan. That is true whether it be a student's aspiration to "try harder next term" or a supervisor's intention to keep her professional judgment free of bias. We recommend instead an explicit, written self-audit.

3. Supervisors should educate themselves about what the "standard" biasing factors are (many of which are discussed above) and give careful consideration to whether, and how, their own behaviour falls prey to, or avoids, those sources of bias.

4. Supervisors should talk openly about COI with their supervisees — both in the abstract, and with regard to particular, concrete COIs. This is an important part of the mentoring process, part of helping advisees learn to recognize and deal appropriately with COI as it arises in their own careers.[5] Talking openly about COI is also a good way of reflecting the fact (noted above) that to find oneself in a COI is not in itself blameworthy: it is an ethical challenge to be understood and mitigated, and from which lessons can be learned.

Advice for Institutions

We offer the following four recommendations for institutions, *in addition to* policies already in place for the disclosing and limiting of financial COI. For some of these recommendations, whether it is best implemented by individual labs, departments, or entire universities will depend on various organizational factors, including size, interdisciplinarity, and so on.

1. Institutions should develop clear guidelines (where these are not already present) regarding such things as appropriate workload and remuneration for graduate students and post-docs working in bioscience labs and appropriate time-to-completion for graduate degrees.
2. Institutions should foster open discussion both of the requirements of good mentoring, and the dangers and varieties of COI. The National Academy of Sciences suggests, for example, that institutions "[s]ponsor more discussions of topics relevant to mentoring, such as professional standards [and] ethical values…." (29)

[5] On the importance of ethics training more generally for bioscience students and faculty, see (28).

3. Institutions should foster a process of self-evaluation or self-audit on the part of professors involved in graduate supervision, regarding the full range of factors known to be liable to corrupt supervisory judgment. Whatever their particular format, the goal of such exercises should be explicitly and emphatically to assist supervisors in self-monitoring, rather than to facilitate greater external scrutiny.
4. Technology transfer offices should implement policies regarding the treatment of students whose graduate research is being done in whole or in part in commercial labs, and regarding limitations on spin-off companies recruiting students prior to the completion of their degrees. We do not have a clear vision of what such policies should look like, but we are certain that such policies, and the multi-stakeholder discussions that ought to inform them, would be useful.

It is critical to acknowledge the different and sometimes conflicting values and objectives of academia and industry, and the concomitant professional roles and responsibilities of supervisors and start-up owner-managers. It is our contention that such relations, and the associated conflicts of interest, are in need of explicit attention from researchers, students, university administrators and industry partners.

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Professors and the management of unavoidable conflicts of interest: don't always need the heavy artillery of policy

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Original version: Williams-Jones B. Professors and the management of unavoidable conflicts of interest: don't always need the heavy artillery of policy. BioéthiqueOnline. 2013;2(4).

Abstract

Conflicts of interest (COI) in the university context are receiving growing attention, but the focus has been largely on problematic financial COI arising from university-industry relations, which clearly need to be avoided. The result, unfortunately, is a pejorative perception of COI as being equivalent to fraud and thus an issue of academic misconduct. In this paper, the aim is to show that while some financial and non-financial COI are particularly problematic and so should be avoided, many are pervasive and actually the norm in academia even if they are still largely ignored and misunderstood. Through a reflection on my own experiences as a university professor, I describe a diversity of common financial, non-financial and institutional COI of varying degrees of risk, that arise in the day-to-day activities of a professor, in order to then consider how these COI can and should be managed in practice. It is essential to attend to the full range of COI and to think about appropriate policies, procedures, or guidelines to prohibit some COI and mitigate the risks of others; but these "hard" mechanisms are only part of the solution. This paper will focus on elucidating the various "soft" mechanisms — such as education, self-awareness, humility, and dialogue (with colleagues, students, staff) — that can empower professors to manage those COI that cannot be prevented or avoided.

Acknowledgements

I would like to thank Marie-Pierre Bousquet, Marie-Josée Potvin and Ghislaine Mathieu for their helpful comments and suggestions on early drafts of this manuscript. Thanks also to the editors and peer-reviewers for their extremely detailed and constructive critique, and their generosity in providing suggestions and examples to further clarify and enrich the text. An early version of this paper was presented at the *3rd Ethics and Health Day: Professional Ethics* (March 18, 2011), organised by the Centre de recherche en éthique de l'Université de Montréal (CREUM) and the Programmes de bioéthique, Université de Montréal. Many of the ideas presented in this paper benefited from ongoing critique and discussion with the Conflict-of-Interest Research Group at the Université de Montréal. This research was supported by grants from the Fonds de recherche du Quebec — Société et culture (FRQ-SC) and the Ethics Office of Canadian Institutes of Health Research (CIHR).

Introduction

The term 'Professor' does not denote a formal profession — as would be the case for doctors, lawyers, nurses or engineers, for example — so there are no professional codes of ethics as such for university professors (even if there may be codes for university staff in general) to guide their behaviour and make them publicly and legally accountable should they breach the norms of their profession. While some professors are also members of formal professions and thus have professional codes of ethics, for the most part professors have to look for ethical guidance in the general professional or institutional norms of academic integrity

(honesty, accuracy, fairness, collegiality, etc.) that they learned during their graduate studies, and through trial and error as they became integrated into their respective academic institutions. Yet, views about "the role of the academy" in society and that of professors are increasingly contested, especially in a context where professors are more than ever encouraged to develop and transfer their knowledge or do research that can be translated into commercializable products (1,2). In the Canadian context, there are a diversity of relevant policies and guidelines that provide a normative framework for professors — e.g., institutional policies on academic integrity/misconduct (3) and conflicts of interest (4), and national guidelines on research ethics (5) and academic integrity (6) — but this guidance may be incomplete, insufficient, hard to access, and sometimes even contradictory. And this is particular the case for conflicts of interest (COI).

In discussions about COI and university professors, we generally think of the issue as being: 1) a problem of academic misconduct, and 2) something that involves financial interests associated with biomedical or applied sciences research. That is, we are mostly sensitive to situations involving the clinician-researcher working on a clinical drug trial sponsored by a pharmaceutical company who is paid for each patient recruited onto the study (7); or the professor who develops a new technology, launches a start-up company and then devotes more time to growing the company at the expense of other professorial responsibilities (8); or the Dean who negotiates a large corporate donation to a research centre in their Faculty, with the implicit expectation that influence will be brought to bear to "encourage" the hiring of certain professors and not others (9,10). Such high-profile cases have led most universities in North America to adopt strict COI policies and procedures to limit the negative consequences of such major financial (and some non-financial) interests on academic behaviour (11). The problem, however, is that these measures give the impression that most if not all problematic COI are financial, and that they are the result of corruption and misconduct by "a few bad apples" (12). Conflict of interest is thus considered bad by definition, and so should *always* be avoided, i.e., the best approach is through the implementation and respect of "zero tolerance" policies and procedures. But this is simply not the case.

A COI, in its broad sense, can be defined as "a situation in which a person has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties as, say, a public official, an employee, or a professional" (13). These factors include not only financial interests, but also the full range of personal factors that can affect judgment or objectivity (e.g., personal pride, prestige, competitiveness) (14). In the context of university research, a COI can arise with "any factor that might tend to undermine a competent researcher's ability to make scientifically reliable judgments concerning research strategy, evidence or conclusions" (15). Further, a determination of whether there is a COI should not be seen as a black or white factual — "yes there is, no there is not" — decision. Not only would such a determination be difficult, and likely very subjective, but it would also set the threshold for determining COI very high and so make the concept hard to operationalize.

Following Resnik (16), a more useful definition of COI would focus on 1) determining the risk or probability of there being a COI given the interests at stake, and 2) distinguishing between those COI that are real (actual) or apparent. A professor, then, has a real COI "if and only if he or she *has* personal, financial, professional, or political interests that have a significant chance of compromising the judgment of the average [professor] in the conduct of research [or other professional activities]" (16), which is distinct from an apparent COI,

which would be the case "if and only if he or she has personal, financial, professional, or political interests that *appear to the average outside observer* to have a significant chance of compromising the judgment of the average [professor] in the conduct of research [or other professional activities]" (16).[6] The most obvious COI occur in situations where professors have financial or personal interests that are likely to influence the objective exercise of their official duties, either as contributors to the shared body of knowledge or as educators (11). Of particular concern are those COI resulting from the private funding of research, whether this be in the form of research contracts, external consulting activities, or participation in joint-ventures (17-19).

Despite the fact that COI can be defined as a "potential for alteration" of the professor's judgment in particular situations, they are not inherently unethical, nor something that should be considered synonymous with academic misconduct, even if they do sometimes lead to unethical behaviour (12). The institutional context of the university makes many COI likely, even inevitable, and they may be unintentional and unconscious. In this paper, I explore a diversity of largely ignored COI — which I have grouped into *financial*, *non-financial* and *institutional* COI — that arise in the normal daily activities of a university professor — i.e., myself. While some COI will be sufficiently problematic (i.e., significant risk of harm to students, colleagues, individual or institutional reputations) to necessitate changes to institutional structures (e.g., implementation of policies restricting certain interests), I will reflect specifically on how those COI that are often unavoidable can and should be managed, and generally without recourse to the "heavy artillery" of COI policies.

Financial Interests

A professor in the Bioethics Program of the Department of Social and Preventive Medicine at the Université de Montréal, my research focuses on issues in health innovation, professional ethics, scientific integrity and the management of conflicts of interest. As such, I will never receive patient recruitment fees for a clinical trial or launch a new technology spin-off company. Nonetheless, my research expertise has led me to be solicited for and engage in paid extramural activities. For example, I have done occasional paid consulting contracts for government agencies (e.g., Genome Canada and Health Canada), have received modest honoraria for sitting on expert advisory committees (e.g., Genome Quebec), and also received honoraria and had my travel expenses paid (with very nice hotels) to give invited presentations at conferences or workshops in exotic locations such as China, South Korea and Red Deer Alberta! The amounts of money involved — ranging from a few hundred dollars to a few thousand — are still very welcome, as too is the opportunity to travel internationally. Clearly these incentives were a small but non-negligible interest that weighed in my evaluation of whether or not to engage in the different activities. This raises a challenging issue, in my mind, namely conflict of commitment, "the umbrella term for issues centering on the allocation of time and energy to fulfill three primary academic roles: teaching, research, and public service" (20).

As many an economist or business person would agree, "time is money". As a busy university professor my "free time" is rather limited, and so for me this time is worth a substantial but completely arbitrary amount of money. I have only one or two days free per 7-day week where I can get to my own research and writing, the rest being taken up by teaching, supervision or administrative responsibilities; so the financial or other incentives required for me to part with my free time are thus relatively high. Why would I want to spend that

[6] Thanks to David Resnik for pointing out the need for this clarification and providing an excellent source!

time working for someone else? It is not as if I *need* the money, given that I have a good salary and benefits. But if the interest of a contract or paid trip is non-negligible and also aligns with my research and publication interests and activities, then it becomes an opportunity worth considering.

The standard mechanisms proposed for dealing with these types of financial COI include:

1. *Financial thresholds*, such as the US National Institutes of Health (NIH) policy requiring federally funded researchers to disclose contracts or fees of more than $5,000, although this does not mean that they will be prohibited (21). But such disclosure thresholds have obvious problems because even $1,500 could be a potentially problematic interest for some professors at some point in time (e.g., a junior professor with a lower salary and substantial debts) and so warrant disclosure, whereas $10,000 for a wealthy senior professor may not be problematic for that individual…while a $100 bottle of wine to a connoisseur could be problematic regardless of their salary! Does the disclosure of only some financial interests necessarily mean that the COI has been managed? Cleary disclosure can only be the first step in a management process. But how (what criterion) is a third party, e.g., my Head of Department, to decide whether my receiving a $1,500 honorarium for an invited presentation constituted a problematic COI, and if so, determine an appropriate management strategy?

2. *Prohibitions*, against "free pens" or paid travel/speaking engagements from the pharmaceutical industry, because they are effective means of generating unconscious positive influence (22,23). But why focus just on Big Pharma, even if their marketing and influence have been notably problematic in medicine? Surely other industries or for-profit/not-for-profit organisations that give away free pens (government agencies, professional organisations) or who pay for travel are trying to influence certain behaviour or create positive feeling on the part of professors? Would the free pen, travel to the capital city and a nice dinner be acceptable when coming from a federal funding agency (but not industry?) for sitting on a volunteer scholarship review committee? Clearly these "gifts" are part of the funder's publicity campaign, aimed at both recognising my participation in an activity that demands a great deal of time and work, and also creating a positive influence, i.e., to entice me to continue participating in such volunteer academic activities.

3. *Disclosure,* such as mandatory annual declarations or posting on institutional websites of faculty COI to promote transparency (24). Again, we have the problem of deciding on what types of financial COI to declare (financial threshold), but also how and in what form they should be presented (e.g., internal to the institution or public). What if people do not declare or even do not know that they are or might be in a COI that should be declared? And just because the interest is disclosed does not mean that its influence has been eliminated and that the COI is managed (25-27).

Thinking in terms of influence, "but for" the financial incentive, there are many activities I would not have taken up; but does that put me in a problematic conflict of commitment that then also affected my professional judgment or objectivity, and so become a COI? Many universities have policies or practices (often not formally codified) that permit some level of outside activities (e.g., consulting) on the part of professors. This may be an implicit recognition that professors are actually underpaid relative to their education (e.g., when compared to the private sector or civil service), or simply an acknowledgement that as they

likely work much more than 40 hours/week (more like 60-80 hours), professors have earned some flexibility in how they manage their time. But this very flexibility can become problematic if external financial incentives led me to spend more than the 1 day/week "do what you want" consulting rule common in many universities and so neglect my other academic responsibilities (a conflict of commitment), and/or prioritise the interests of those for whom I am consulting over my responsibilities as a professor (a COI).

More diffuse is the general pressure on professors to perform in order to progress their career and obtain higher salaries, even when there are no financial performance bonuses. Recognising that "what really counts" for promotion is grants and publications, there is every interest in spending one's time on research, publications and grant writing, to the detriment of teaching, supervision or collegiality (participation on various departmental or faculty committees). Here, then, the financial interest is in obtaining a better salary and more grant funds, and the conflict is that this interest skews behaviour towards a subset of a professor's academic responsibilities (and judgment about which are important) at the expense of others (e.g., students' interests) (20,28).

My own experience with the management of these financial interests has made it clear that formal annual disclosure policies that require filling in a form are a very limited part of the solution, especially when there is no subsequent plan for managing the situation. Instead, what has helped me to address these COI has been self-awareness of my own interests and reflection about how these interests can conflict with my other responsibilities. For example, in accepting paid travel to an interesting destination, or a consulting contract to perform a particular research project, I ask myself the following questions: Does this activity align with my current research interests? Is it going to distract me from my other responsibilities? Do I have time? How can it benefit my students or colleagues (e.g., funding for students, network)? And when uncertain of the answer to one of these questions, I consult my colleagues. This self-questioning necessitates a significant degree of reflexivity — even brutal self-honesty — and the humility to share one's concerns and seek advice from colleagues in order to see whether a particular COI is problematic, and if so, determine how it can be best managed. It also requires recognising that some interests are especially problematic, may be hard to identify through reflexivity (its very hard to admit, as a professor, that one may be biased!), and so should be avoided or even prohibited.

Non-Financial Interests

From my perspective, the COI that I find the most challenging to manage in practice — and thus the most intellectually interesting to reflect upon — are those that are non-financial and have to do with human interactions and relationships. As a university professor, most of my time is spent engaging with various people in diverse contexts (e.g., students, other professors, administrators, support staff), and as such I am regularly implicated in a diversity of COI that are more or less problematic. In this section, I will focus on three types of relationship: 1) professor-student, 2) professor-professor, and 3) professor-institution.

1) Professor-Student Relationship

My teaching is all done in the context of a graduate program, so it is often the case that students taking my courses are also ones who I supervise for their Masters or PhD projects. As such, this creates an important COI that has implications for both the student in question, the class as a whole, and the trust they have in me as their teacher/supervisor. I invariably know "my graduate students" much better than the other students in my class, so there is a potential to be biased (e.g., be more generous) in my evaluation of their assignments as

opposed to those of the rest of the class. Because I am aware of this potential for positive bias, I might also be overly severe in evaluating my own students' work, "over correcting" as it were and thus unfair in comparison with my evaluations of the work of their fellow students, because "I know my student can do better!" This type of COI can be thought of as being at one end (i.e., least problematic) of a spectrum of professor-student relationships.

More problematic is the situation — which I have had recounted to me by colleagues — where a student in the class is in a close personal relationship with the professor (e.g., child, spouse). In this case, it is appropriate that the professor not grade the student to avoid all real or perceived bias; better yet would be for the student not to take the professor's course, thereby avoiding all appearance of COI. Similarly, in the case where the student is the child of a colleague or a neighbour, and especially where there is a longstanding relationship (e.g., having watched the child grow up), it would make sense for this student to be evaluated by another colleague or teaching assistant.

In both cases, however, there is a need for a case-by-case analysis and an intervention that is proportionate to the risk. To prohibit, without exception, the participation in a course of students who have a close personal relation with the professor could unduly penalise some students, especially when the course is obligatory, and no alternative courses are available. In a large class setting, where there are teaching assistants, it is possible to have the student graded by someone not in a close personal relation, although effort will still have to be made to ensure that there is no favouritism on the part of the grader towards a student they know to be in a close relation with the professor. But as in my previous example about having students in my graduate seminars, it becomes far more challenging when there is only one evaluator (the professor) and a small cohort of students. Overall, I would suggest that the perception of partiality may be less problematic than the pressure that the professor might *feel* to be more favourable towards this student (i.e., to be nice or not overly demanding to the child of friend/colleague), regardless of whether there are any *actual* pressures from the friend or colleague.

At the other end of the spectrum of problematic cases are romantic relationships between students and professors. Even if the relationship is fully consensual between two adults, the power imbalance will be such that other students or colleagues will invariably question whether the professor abused their position of authority to seduce the student, even if in fact it were the reverse situation (29). Moreover, there may be a breach of confidence that jeopardises the trusting relationship that should exist between a professor and their graduate student. A romantic interest, I would argue, undermines the professor's ability to actualise their fiduciary responsibility to work in the best *academic* and *professional* interests of their student, as would also be the case for financial COI (e.g., the student also works in the professor's spin-off company). The risk of biased judgment — not to mention accusations of sexual harassment — and the associated loss of credibility and trust on the part of the class and colleagues (and towards the Institution) is simply too high to be permitted (30).

Most institutions would rightly condemn — and even punish as academic misconduct — romantic relationships between professors and undergraduate students, because of the power differential (if not necessarily also an age difference) and the very negative perception of bias on the part of other students and colleagues (31,32). More challenging is the case with graduate students, who tend to be older and more mature (many of my graduate students are my age or older), and who can develop close and long-term working relationships with their supervisors that sometimes lead to romantic feelings. Should a consensual romantic relationship develop during the course of a supervision, a reasonable

solution would be for the student to change directors, and for the now former supervisor to avoid evaluating the student in all other context (juries, scholarship competitions); nonetheless, the appearance of COI may still be very hard to eliminate (33). I would thus take the strong position that professors should, if at all possible, avoid teaching and never supervise graduate students with whom they have a close personal relationship (e.g., filial, romantic, or business).

But to return to the initial and arguably less problematic but more common case of my teaching graduate students who I also supervise, it would be impractical — and probably unwarranted given the level of risk of bias — to require me to not grade these students. In practice, this would mean asking other professors to grade students in a course that they do not teach, adding a responsibility that is normally assumed only in cases of student misconduct (e.g., plagiarism) or a disagreement on a final evaluation. One possibility might be to use evaluations that a blinded review procedure, so that students' identities are hidden during the evaluation process (e.g., stripping of identifiers such as name, ID number, etc.). While this could certainly work minimizing a risk of bias in the context of written exams, it would be much less practical for essays because I will likely know the student's research interests and writing style, and impossible for in-class presentations. These last two evaluation mechanisms are commonly used in the humanities and many social sciences, and ones that I invariably use in my graduate courses. My management approach has thus been to make a conscious effort to be as fair as possible in my evaluations, recognising my own bias towards being either overly generous and/or more demanding of the students I supervise.

Given the significant academic liberty that professors have in the design and conduct of their courses (and thus confidence in their judgment), as well as the substantial subjectivity in evaluating written work, self-awareness and experience are likely the best management approach when it is not possible to blind the work or have it evaluated by a third party. But transparency is also important to building and maintaining trust in the face of actual and unavoidable COI. So in these situations, I discuss the COI with my class at the beginning of term. Disclosure becomes "a teaching moment" or pedagogical tool to help introduce students to the notion of COI in general, and the risks or harms that need to be avoided (e.g., positive or negative bias, favouritism), and justice and equity in student evaluation (e.g., merit vs. egalitarianism) that can be compromised when COI are not managed appropriately.

Besides teaching or graduate supervision, there are many other situations in the professor-student relationship that regularly put professors (including myself) and their students in potentially problematic and often unavoidable COI (28).

Publications

Unlike some disciplines in the humanities and social sciences, in the applied and health sciences — and for my purposes, in bioethics — it is both possible and valorised to co-author papers with students. The obvious positive aspect is that this helps students learn how to write and publish, and to build their academic experience, credibility, and confidence. Co-authoring also benefits professors by allowing them to produce many more publications per year than if they were publishing alone; but for my student co-authors, I would be unable to publish the 5-7 articles per year that are considered a "normal" publication record for a tenured professor. Given the very real pressure on professors to "publish or perish", this could lead to important COI. A professor might push a student to spend an unreasonable amount of time on a manuscript to get it into the top journal, at the expense of the student's other activities/interests, namely completing their thesis in a timely fashion, a case I've frequently

heard from graduate students in the health and applied sciences. Or the professor might pressure the student to be named on all papers in the thesis, regardless of the professor's actual level of contribution, something that is also very common in the applied sciences. Less overtly problematic, but equally sensitive, is the challenge of equitably allocating authorship in team publications, where the professor and students may all have interests in being first author, and where (inter)disciplinary norms may be missing or conflictual (34). The issue of publication authorship can lead to COI when trying to determine who should be first author (and the order of other authors): myself as the researcher and professor who's sometimes also paying the students as research assistants, or one of the students who "needs the publication more" than I do, regardless of their actually contribution? My solution has been to discuss, from the beginning and at different moments during any writing collaboration with my students and research teams, the issue of authorship (34). I make it clear that author order is always up for re-negotiation as the work proceeds and will depend on a person's level of involvement; the first author is the person who drafts the paper and "runs the project", and that is rarely me because of my lack of time, thus my interest in co-authorship. Nor do I assume nor require that I be a co-author on every paper — even if in practice I often am named on the paper — included in my graduate student's thesis.

Research Assistants

In conducting my research and in publishing, I invariably work with a small team of research assistants (RA), some of whom I also supervise. This is a direct benefit to me because it brings in extra expertise and support to advance the project, benefits students who get research experience and funding, and allows me to publish at a higher rate (more collaborative publications). But how should I choose who to hire as an RA? Can I legitimately favour my own students who I know well, am responsible for and have an interest in seeing financially supported and advancing in their careers? What about other graduate students, who are equally in need of funding and research experience, but are not part of a research team; do they not also deserve a chance (an issue of equity, and not a COI)? Finally, in hiring students as RAs, there is a clear change in the power relation and in our respective roles, because I am paying their salaries; they are students but also employees, and I am a supervisor but also an employer (28). There is pressure for them to perform and concentrate on advancing my research agenda, but at the same time I am also interested in their success and so that could lead me to be at times too lenient (e.g., with regards to their other commitments/interests, or author order on publications) and so undermine the timely work on the project, and thus the interest of funders in seeing the project completed.

The numerous and diverse interests that arise when hiring an RA (whether their thesis is supervised by me or not) can and often do conflict. At the heart is an issue of trust, both with regards to the student with whom I work and to the funding agency (and thus the broader society) that financially supports my research. I honestly choose to "play favourites" and so select the best students I encounter in my teaching, and preferentially those who I have already agreed to supervise for their Masters or PhD theses. In this way, I support those students to whom I have a direct obligation (e.g., supervision, mentoring, financial support where possible), who I know to be competent, and with whom I am able to work effectively; and in so doing, I also am more likely to succeed in my research activities and thus meet my obligations to research funders. As with issues of supervision and authorship, the inevitable COI between my and the RA's interest in publishing, gaining research experience, and also meeting the interests and demands of my research project are managed through regular and open dialogue. But it is also important to recognise that my priorities and those of my students will diverge at times, at which point it becomes a question of negotiating tasks and

timelines, sometimes finding other personnel, or accepting a slower or different productivity than initially planned. In my experience, this is invariably the nature of research projects, where the plan we start with may not be the one we complete; the inevitable COI are thus managed through dialogue, compromise and adaptation, and the result is still excellent productivity.

Letters of Reference

Professors are regularly solicited to write reference letters for their students, primarily for scholarship applications, but also eventually for jobs. Given my positive regard towards my students, and my real interest in seeing them succeed — it is personally very rewarding, but also reflects well on my own academic prestige — how objective can I really be? What should I do when I have multiple students asking for letters for the same competition; should I accept to write all letters, as strong as possible for each, or only accept to write a letter for the "first through the door"? Should I accept to write letters for students who I do not think are strong enough "just to be nice" or to not discourage them? (35,36)

My approach has been both self-interested and honest: for students who I do not think strong enough for a competition, or who I do not know well enough, I tell them that I cannot write them a strong enough letter and discuss where I think their weaknesses are and how these can be improved. I do not waste my time writing weak letters that will actually hinder a student's application. For those students who are strong and whom I know well (even if I am not their supervisor), I accept to write them all letters, even if they are competing for the same scholarship, and make it clear to all that I will write the strongest letter possible. The management of this COI is through transparency, but also reflexivity, as I try to be as honest as possible about each student's strengths and weaknesses while also writing the best possible letter.

In an attempt to mitigate the inherent favourable bias in letters of reference, some institutions (departments or funding agencies) have moved towards requesting numerical or grade-based evaluations instead of written letters of reference. But these are, to my mind, no less subjective than the traditional letter where I enumerate the excellence and diverse skill sets of my students, particularly in a field where multiple competencies are required (37). Through my students, I am clearly competing with other colleagues who are also promoting their students' interests in succeeding. In a sense, then, there may be a market competition at work such that the best student dossier (grades, project proposal, letters of reference) wins out, thus eliminating (minimizing) the problem of bias, i.e., if all professors write strong but honest letters of reference. However, in a context of grade inflation and pressure towards hyperbole in reference letters, if professors let their own interest in their student's success led them to unreasonably promote less competitive students, this market analogy fails and difficult COI remain.

Perhaps even more challenging is the case of the extremely productive student who also has some personality conflicts. Knowing that my letter of reference is an important part of an application package (e.g., for a scholarship, a job), do I leave out certain weaknesses such as the fact that the student can sometimes be "difficult" in a team setting, or even avoid all reference to collegiality, and instead play up their excellent publication record because the truth would not be an unqualified recommendation? The conflict is thus between being honest and providing the information that a reviewer (i.e., a fellow colleague, or even myself as a reviewer) would want to know and wanting the reviewer to positively evaluate my student. The reality is that some letters a professor must accept, and they will be very hard to write; the tension cannot be evacuated from the situation, and so the professor may remain

genuinely conflicted about what is the objective truth and whether they should express it in a letter of reference.[7]

Aside from completely eliminating letters and simply relying on student CVs (which raise their own problems with objectivity and "padding" or inflation), guidance for addressing the COI raised in the context of letters of reference will likely be found in norms of academic integrity and collegiality (which have obvious limitations), to some extent in professional self-interest in avoiding a potential loss of credibility should the professor gain a reputation for promoting mediocre students. But it will also be important for the professor to be honest and to try to write the strongest letter possible, while recognising that they will have to grapple with difficult questions to which there may be no clear solution.

Scholarships

At the level of granting agencies, it is obvious and practical to require that supervisors not judge their own students in scholarship competitions; i.e., professors *recuse* themselves from the review process (the do not evaluate their own students) and often even leave the meeting while the candidate is being evaluated, so as not to bias or even give the appearance of biasing the discussion and decision making. There are invariably sufficient committee members present to ensure that all students are fairly evaluated when one member of the committee has to leave because of a COI; and the risk to the credibility of the funding agency is far too great to permit even the appearance of COI. By contrast, the management of COI in internal institutional scholarship programmes can be much more problematic. Whether as part of a responsibility in my graduate program, or through my active involvement in various research centres, I am regularly called upon to evaluate student dossiers for scholarship competitions, and often I find myself evaluating and ranking my own graduate students, or students who I have taught. But were we to apply the rule of the large funding agencies, there might simply not be enough professors around the table to do the evaluation…and often many members of the jury have their students in the competition!

An alternative would be to remove this responsibility for evaluating scholarships from programmes or departments and place it within the hands of a more distant body, such as the Faculty of Graduate Studies. But then, in essence, this would require replicating internally the structure of the funding agencies and thus necessitate the constitution of review panels with the requisite subject/discipline/methodological expertise to fairly judge the dossiers; the solution to the COI is thus very costly in terms of time and personnel, and probably impractical. In practice, what we often see is local (centre, department) evaluation, where professor COI is managed but not eliminated through transparency (declaration) and a balancing of interests through competition. Committee members try to evaluate, as best as possible, the candidates in hand while being clear about their own interest (their own students' success) in face of the interest of their colleagues. Alternatively, professors could refuse to write reference letters for competitions on which they will be evaluators. But this would then put their students at a competitive disadvantage — compared with students' whose supervisors are not on the scholarship committee — in presenting the best possible application, something that is particularly problematic in small programmes (my situation) where it may already be difficult to obtain strong letters of reference because there are only a few professors who teach most of the courses.

My own career advancement benefits when my students graduate and succeed, so a pervasive interest — and thus COI — arises from my professional relationship with my

[7] Thanks to Daylian Cain for sharing this excellent — and challenging — example!

students. I might over-promote them beyond what they are actually capable of accomplishing or may help them too much in their research and publication activities. But I also have a responsibility as a professor — whether as supervisor or teacher — to help my students acquire the knowledge and skills necessary to progress in their studies and chosen career paths. The management of the aforementioned COI is thus — as in the case of letters of reference, or scholarships — an issue of academic integrity on my part and requires self-awareness and honesty about my own interests. In some cases, it can be possible to include other expert evaluators to form the scholarship committee (something we have done in my Program on occasion), and thus eliminate the need for professors who are also supervising candidates to participate in the jury. But this will not always be possible. As such, the issue of internal scholarships and fair evaluation procedures should be a subject for ongoing discussion amongst colleagues (e.g., to identify best practices and procedures). In the context of specific juries, professors must disclose their own interests, and discuss those of the students and colleagues involved, in order to help ensure that awareness of our respective interests leads to fair and honest evaluations, and the maintenance of professional and collegial relationships.

2) Professor-Professor Relationship

The academic environment is a competitive one, and it is likely impossible to succeed without a healthy dose of professional ambition. Even in the Canadian context, where professors have relatively good salaries and access to grant funding through provincial and federal funding agencies, there may be competition that could result in COI. The most obvious COI (whether financial or non-financial) arise in the context of peer-review, whether for grants or in publications, and these are invariably managed, if imperfectly, through disclosure mechanisms (27). This obviously requires honesty on the part of a reviewer to disclose an interest, whether favourable or not, with regards to the submission of a colleague, friend or competitor/adversary. Evaluating a grant application or peer-reviewing an article takes substantial time and energy, is invariably volunteer work, and while important to the functioning of the academic community, is not highly valued in promotion. So an important factor supporting the effectiveness of the COI disclosure mechanism is that it can give busy professors who are in a COI an easy way to get out of work that they might otherwise feel obliged to accept!

The downside of not evaluating a paper or grant due to COI can be the problem of expertise, which is particularly challenging in very specialised areas of research where all the researchers know each other. Blinding of the review process may work in large fields, but becomes completely impractical in other areas, such as for scholars working in bioethics in Quebec and English Canada; the community is simply too small. So for example, in the journal *BioéthiqueOnline* [now the *Canadian Journal of Bioethics / Revue canadienne de bioéthique*] of which I am Editor-in-Chief, we have opted for a policy of full transparency in our evaluation process (i.e., authors, editors and peer reviewers are clearly identified during the full review process and named on the final publication), and disclosure of all COI on the website and on individual publications. We accept that students and colleagues will sometimes be in COI regarding the evaluation of manuscripts — we invariably know each other well, having worked together — and so declare these interests so the reader can evaluate whether they biased the quality of the work published in our journal.

In my experience, much more problematic and harder to manage are the professor-professor relations that have to do with teaching and administrative responsibilities, collaborative opportunities, competition for limited resources, and ambition to succeed and be respected

by one's peers. Some of these may be simply issues of professional integrity and collegiality, but others can lead to important and very problematic COI.

Workload

Having recently received tenure in 2010, I still very well remember the experience of being a new and junior colleague in my department. In research universities, junior professors are often protected during their first few years from assuming too many administrative or teaching responsibilities, because they should be working to both build their courses and establish their research and publication records, with a view to contract renewal (after 2-3 years) and eventual tenure application. In practice, though, the arrival of "the new kid" in a department can be an opportunity for more senior colleagues to download responsibility for courses they no longer wish to teach, or participation on committees that they find uninteresting or time consuming. At the same time, junior colleagues may not know the departmental history or politics, feel ill-placed to "say no" to "requests" from colleagues, or simply be poorly placed to judge the "good learning experience" of sitting on a particular committee. Often this is also an issue of being presented with too many good opportunities (i.e., too many interests) — this was certainly my experience in the first few years — and being unable to judge which ones are worth the investment and which opportunities are too costly in terms of time, energy and stress. There are many conflicting interests pulling a professor in different directions, and sometimes these become COI when junior professors feel pressured (whether or not intentional) to accept responsibilities that they would otherwise not, if they were being more self-interested.

A challenge for directors of departments, and colleagues more generally, is to ensure an equitable distribution of teaching and administrative responsibilities, while also recognising that colleagues will have different interests depending on where they may be along their respective career trajectories. The solution is, first, a recognition that junior colleagues are particularly vulnerable in the early stages of their careers, and so their interests should be favoured over those of more senior colleagues, especially when these conflict (something that could be recognised in departmental procedures or even collective agreements). The corollary could be formal or informal mentoring arrangements, which I have seen in a colleague's department, where a more senior colleague is paired with a junior colleague to guide them through their introduction into "the academic game", teach them how and when "to say no", and so be able to better recognise and manage the diversity of interests — some of which will conflict — that are part of the life of a professor. In so doing, departmental colleagues also explicitly recognise that those who are more senior may be in real COI (whether or not intentional) with regards to the attribution of academic responsibilities to/by their junior colleagues.

Research opportunities

Similar to the case with students, professors may be inclined to favour their friends over other colleagues (and even marginalise adversaries) when it comes to building research teams, inviting colleagues to be part of research networks, or collaborating in multi-authored publications. Now many of these choices might be considered reasonable, even prudent, and not a COI. Professors are not forced to work with each other, and it would be foolhardy to collaborate with someone who one disliked and distrusted; professors can, one might argue, always work on other projects and build their own teams and networks. Yet, I have seen junior colleagues systematically excluded from groups or networks, and had serious impediments placed in their paths that even jeopardised career advancement (promotion, tenure, etc.). The contrary is also the case, where promising junior professors are solicited

by senior colleagues to participate in large research teams or networks in order to expand the ranks of productive CVs, but also out of an honest desire to collaborate with the best (new) researchers in the field. As in the case of administrative or departmental responsibilities, junior professors may inappropriately weigh the prestige and "honour" of being invited to join a high-profile team, against the work involved (committee meetings, reports), the actual resources provided (less money than promised), or the loss of time to focus on their own research and publications. In some very specialised fields, what might normally be productive competition can become vicious and mean spirited, and when some of the parties involved are in positions of power with regards to grant funding or promotion, there can be cases of serious academic misconduct, including COI.

In these cases, formal policies or regulatory mechanisms addressing academic integrity/misconduct and COI will likely be of only limited utility, because the threshold (and cost to those actors involved) necessary to invoke these mechanisms will be too high in all but the most extreme cases. More effective is the lived experience of professors who have gone through or witnessed problematic situations. By sharing such experiences with other colleagues, particularly those at the beginning of their academic careers — whether they are still graduate students or junior professors — it becomes possible to name and so identify the interests at stake and the cases where they create problematic COI. Not to be ignored, however, is the power of a good or bad reputation and the view of one's peers. Being forewarned by a senior colleague that a particular research team is either an abusive or an excellent environment is the sort of guidance that can both support a junior colleague and also mitigate some of the COI that are omnipresent in research.

3) Professor-Institution Relationship

University professors in Canada and in the US have enormous academic liberty and independence, both with regards to what and how they teach, and the subjects of their research. While I may have discussions with my colleagues and Head of Department about the courses needing to be taught in a given academic year, it is up to me alone to design my syllabus and decide on the most appropriate pedagogical approach. Similarly, my choice of research interests, and what grant applications or articles I decide to write, is a purely personal decision, even if I regularly receive helpful suggestions from colleagues and research collaborators. My relation with the institution — that is, with the Department of which I am a member, and with the University who is my employer — is one where I have substantial freedom.

Nonetheless, COI can arise in this relation when certain interests, e.g., personal ambition in advancing my career, are placed above those of the institution, whether it be the Department or Faculty. The most obvious examples are conflicts of commitment, when professors do not "pull their weight" in teaching, graduate supervision or committee work, and as a result other colleagues are "left to pick up the slack". Given our independence, as professors we may know little about how much work our colleagues actually do. The Head of Department will have a better idea, and blatant examples are all too apparent, e.g., when colleagues are rarely present at departmental meetings or on committees. But it may be very difficult in practice to know which colleagues are working hard on all aspects of the profession (teaching, research, administration, public service), and which are focused primarily on one aspect, usually research. It is particularly hard to determine when a healthy professional ambition that supports a successful career path (something to be encouraged), becomes a self-centred interest that will conflict with the interests and objectives of the institution.

To be fair, while professors have a range of activities required of them, the important aspects for career progression — particularly in research-intensive universities — are invariably publication record and success with grant applications; teaching and administration, while expected and important for the good functioning of the institution, are much less valued by promotion committees. So professors, especially those who are not yet tenured, must regularly juggle with the pressure — and potentially conflicting interests — to on the one hand "publish or perish", and on the other be a "good colleague" and participate on committees (administration), while also teaching their courses and supervising graduate students. The flipside is that once tenured, a professor cannot be fired baring cases of gross misconduct; there may thus be a real interest to take it easy once a professor has tenure (e.g., more time consulting, absence from departmental committees, neglect in student supervision). In practice, this is likely rarely the case because the competitive work ethic and ambition necessary to obtain tenure becomes ingrained in the professor's professional identity! And with this comes responsibilities and even an unconscious pressure to keep students involved in research and in publications (e.g., through co-authorship) and to keep research teams funded through competitive grant applications, which bring with them their own risk for COI.

Such conflicts of commitment and COI can often be managed through social or collegial mechanisms, such as the protection of junior colleagues from undue demands (as mentioned previously) or the indirect sanctioning of colleagues who do not do their share (e.g., placing them on necessary but unpleasant committees, or removing them from decision making contexts). Structurally, institutional changes could be made to valorise the full range of activities required of professors, such as by ensuring that all aspects are weighed appropriately in promotion, or by providing certain benefits (e.g., teaching release) for those with disproportionately high administrative responsibilities or graduate supervision workload (something that is done in my department). Academic liberty and autonomy, while a cause of some problematic COI (e.g., ambition that leads to conscious and unconscious self-interested behaviour and conflicts of commitment), can also be a strong protective factor because it can empower professors to "say no" to some demands of their institution (e.g., from the Department or Faculty). This does not mean that clear rules are not necessary, e.g., to manage particularly problematic financial/non-financial COI or conflicts of commitment, but that many COI will be managed by reference to other principles or values (e.g., academic integrity).

Institutional Interests

As Director of the Bioethics Program — a graduate program with more than 70 students at the Masters and PhD — I have an additional administrative responsibility that most professors do not have, namely, an obligation to defend and lobby in the best interests of my Program. Specifically, I work to promote the best interests of our students, my colleagues and my field of specialization. In a department with other graduate programmes and other specialties, there can be differences of opinion and even conflicting interests — if not actually COI — with regards to the importance of other fields of research or institutional priorities. This becomes particularly evident in a context of limited resources, both with regards to operational funds and the human resources needed to ensure my Program's good functioning. Along with the other program directors, I may be competing to obtain sufficient funds to hire sessional lecturers or teaching assistants for my Program's courses. Even more sensitive is the hiring of new professors, where vigorous and even acrimonious debate can occur about departmental priorities and the needs for particular areas of research and teaching. In these situations, there may be a direct conflict between my interest in and responsibility for the

Bioethics Program (i.e., ensuring that there are sufficient funds and personnel to meet our objectives), and the interests of my other colleagues, the other programmes, and the Department more generally, the result of which could be COI in some decision-making contexts.

As with the previous types of professor-relationship, many of these COI can be managed effectively through full disclosure and open dialogue. In departmental meetings or in discussions with the Head of Department, it becomes readily apparent what are my personal and my program/institutional interests, and these get "put on the table" and so have to compete with the interest of my other colleagues. If I can mount a convincing case to my colleagues that my Program's interests should be prioritised, then the conflict — if there is one — is dealt with in a democratic fashion, and one that my colleagues should accept. Problematic, however, are those situations in which professors are not clear about their interests (either to themselves or to colleagues), or worse yet, when backroom deals are made between members of a department and so the diversity of interests cannot compete in the open and on a level playing field; the decisions made by key actors in the department may be biased, leading to harm to certain actors (e.g., some programmes or professors are disadvantaged) and then a loss of trust on the part of department members and even other colleagues. These situations do occur, but in a department with a strong democratic culture, and a practice of discussing and documenting (in minutes, with departmental policies) good practice, these COI can be better managed.

Conclusion

Conflicts of interest are receiving growing attention in the university context, but unfortunately, there is still an overwhelming pejorative perception of COI; they are too often seen as something equivalent to academic misconduct (and so to be avoided at all costs!), and as being primarily financial in nature (12). This paper has aimed to show, in some detail and through a reflection on my own experiences as a professor and director of a graduate program, that COI are not only pervasive in the university, but that they are actually a normal part of the life of professors; while COI raise important concerns about bias and credibility of judgments, in many cases they are unavoidable. In large part, I suggest, COI are due to the reasonable and unavoidable ambition of professors in their own career development, and in that of their students, colleagues and department. The challenge, then, becomes one of identifying those COI that are problematic — and in making the implicit, explicit — and so avoiding COI when possible and when not, figuring out how to live with them while minimizing the risk (e.g., harm to personal or professional identity, trust, institutional reputation).

It is essential to attend to the full range of these COI — financial, non-financial, or institutional; intentional or unintentional — and to think about the appropriate policies, procedures, or guidelines to mitigate COI and manage them when they cannot be avoided. Yet, there are important limits to such "hard" mechanisms. Formal policies are essential to describing the "lay of the land", to marking the boundaries for what is considered acceptable behaviour and should be accompanied by procedures and training to deal with misconduct or unethical behaviour. It is through policies and procedures that an institution can make explicit those norms and values that are implicit, and often unarticulated, and so work towards developing and ethical culture for the institution. Nonetheless, most of the tools or approaches I have outlined in this paper — and which I have used myself — are "soft"; that is, they rely on individual integrity, judgment, self-awareness or reflexivity, humility and collegiality (38). This is because most of the COI encountered in the university context are

not the extreme cases that unfortunately make the headlines, where the risks or harms are great, and so where formal rules and policies are clearly necessary.

The COI that professors regularly encounter — whether it be in writing letters of reference, or in collaborating with students or colleagues on research projects — are important and need to be managed. But were we to implement rules or policies for all these cases, we would unduly tie the hands of professors, and the costs would likely be higher than the risks we are trying to avoid; nor would such policies be sufficiently flexible or adaptive to respond to all possible scenarios. A much better approach, I argue, is to empower professors to recognise those COI that are "out of bounds" — the ones normally addressed in institutional COI policies — and also be able to identify and evaluate those that are pervasive and so need to be managed. This, then, means giving much great attention to education — educating the educators, as it were — and providing practical tools and guidance to deal with common but problematic situations. It means bringing COI out of the darkness and accepting that it often has to be lived with and managed, but never ignored, nor systematically dealt with as fraudulent practice. It also means being sufficiently humble to recognise our own limited objectivity (39), and being open to discussing with our colleagues and our students those COI that cannot be avoided, in order to find the most effective and appropriate means for their management.

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A procedure for managing conflict of interest when forming thesis juries

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Original version: Williams-Jones B. A procedure for managing conflict of interest when forming thesis juries. BioéthiqueOnline. 2017;6(7).

Summary

Conflicts of interest in thesis juries, when not identified and appropriately managed, can lead to an uncritical and unfair evaluations that can then undermine trust in the process and threaten academic credibility and institutional reputation. This Commentary presents and justifies the choices made in developing a practical procedure to identify and manage conflicts of interest in the formation of Masters and PhD juries in the School of Public Health (ÉSPUM) at the Université de Montréal.

Acknowledgements

Thanks to Lise Lamothe and François Béland for their constructive feedback on the manuscript, and to members of the Graduate Studies Committee in the School of Public Health (ÉSPUM), Université de Montréal, who provided feedback on drafts of the procedure and declaration form presented in this paper. Thanks also to the peer-reviewers and to the editors for their very helpful suggestions for restructuring and clarifying the presentation of the paper. The procedure presented here is the practical culmination of more than a decade of research with members of the Research Ethics and Integrity Group (formerly the Conflict-of-Interest Research Group), which was supported by grants from the Fonds de recherche du Québec — Société et culture (FRQ-SC), the Ethics Office of the Canadian Institutes of Health Research (CIHR), and the Office of the Vice Principal Human Resources and Planning, Université de Montréal.

Introduction

In 2012, I published a case study entitled Choosing Thesis Juries: The Costs of Taking a Strict Line on Conflicts of Interest (1), inspired by my first experiences as a professor in forming thesis juries for my Masters and PhD students at the Université de Montréal. The heart of the issue in this case study was the challenge of working with a very rigid rule for managing conflict of interest (COI) that prohibited the inclusion of jury members with whom the student or supervisor had published within the previous 5 years. The aim of this rule was clearly to avoid supervisors "stacking the jury" with their friends or those who might be perceived as giving an unduly favourable review, because such behaviour could 1) reduce the quality (e.g., critical review, objectivity, fairness) of the thesis evaluation process (e.g., by permitting lower quality theses to be accepted or even highly ranked), 2) undermine trust by members of the institution in their colleagues (or even entire departments) found have had problematic COI in their juries, and so 3) lead to an important loss of institutional reputation, from the perspective of both institutional members and the general public. Research institutions valorise academic integrity, scientific rigour and public credibility and so cannot permit COI situations to continue to be poorly managed without incurring great risk.

While having the advantage of being clear, this rule was limited in its scope because other potential COI were ignored and its application relied on a literature search to detect

collaborations. More problematic, however, was that it resulted in the blanket exclusion from thesis juries those professors who were experts in the field but had "unfortunately" already collaborated with the supervisor and/or student. This situation is especially challenging in very specialized fields such as bioethics or public health where there is a limited pool of potential experts and exacerbated in a context where the language of the thesis is not English, such as is the case at the Université de Montréal, a French-language institution. The case study sought to highlight the diversity of COI that can and should be taken into consideration in forming thesis juries (e.g., authorship and grant collaborations, personal and professional relations, practical considerations, issues of expertise and fairness), and that are part of the broader set of real and potential COI that professors face in their day-to-day activities (2,3).

With the creation in 2013 of a new faculty-level School of Public Health (École de santé publique) at the Université de Montréal — made up of the Departments of Social and Preventive Medicine, Health Management, Evaluation and Health Policy, and Environmental and Occupational Health, that were previously in the Faculty of Medicine — an entire administrative infrastructure (e.g., appointment of a Dean and Vice-Deans, creation of various policy committees) had to be developed. One of these structures, which I joined in 2013, is the Education Committee (Comité des études), chaired by a Vice-Dean and which brings together all the program directors in the School. The committee is responsible for oversight and approval of developments and changes to programs, but also for establishing policies and procedures. An issue that arose in 2014, following a series of major reforms to the Masters and PhD programs, was the need for standardized Faculty-wide procedures to guide the composition of thesis juries, and in particular, to deal with issues of COI. As my research team and I have been working on the ethical management of COI since early 2005, I volunteered to help create a practical procedure that could be used across all the programs in the School of Public Health.

Our previous research examining institutional COI (4,5) and research integrity/misconduct policies (6), as well as focused searches of the Université de Montréal policies (whether the top-level policy University COI policy or those general documents produced by the Faculty of Graduate Studies), found general policies but very little clear guidance beyond the recommendation to avoid COI. Yet, as our research clearly showed, without an awareness that COI is an important problem (i.e., because it can bias decision making and undermine trust) and that COI situations must be identified so they can be managed appropriately (e.g., prevented, or the risks mitigated), even the best policies are "not worth the paper on which they are printed".

From awareness that there is a problem in need of management flows the obligation on the part of institutions to develop and implement clear, understandable and practical procedures that can effectively manage COI when they cannot be avoided, as is very often the case in academia. However, all too often the declaration of COI is seen as a panacea, which is particularly problematic (7). Empirical research by Cain and colleagues (8,9) has shown that disclosure of COI may lead to a form of "moral licensing" both on the part of individuals who disclose COI ("I've declared my COI so the problem is gone, right?") and others ("He disclosed his COI, so he's ethical, and the situation is fixed."). In practice, disclosure is still necessary, but it is not sufficient. Policies and procedures must also include evaluation mechanisms, such as review by other parties to verify and determine the level of risk posed by the COI and ensure that especially problematic COI are avoided (i.e., some jury members excluded), and that those COI that are more acceptable are managed appropriately (e.g., selection of different jury members to "balance-out" or mitigate the COI). Awareness raising

off all stakeholders involved is also necessary so that as jury members striving for objectivity or neutrality in their review of a thesis, they keep in mind that this is impossible and that biases may still remain (i.e., reflexivity).

Building on my team's previous work analyzing the language of institutional COI policies (10), and our more recent collaborations with the Office of the Vice-Principle Human Resources and Planning to develop COI educational resources and a new procedure for the annual Declaration of interests, I developed a short and practical procedure to better manage the formation of thesis juries. To be effective, the procedure had to explain the nature of COI (e.g., personal, financial, institutional, ideological) and give clear examples (i.e., awareness raising), and provide a clear and detailed decision-making process (i.e., be practical).

A first draft of the procedure was produced in October 2014 and sent to the Vice-Dean of Education, Professor Lise Lamothe, and the director of the PhD in Public Health program, Professor François Béland, both of whom provided substantive feedback and additions. A revised version of the procedure, with the addition of a Declaration form, was then circulated to members of the Education Committee before approval in November and a subsequent Faculty-wide roll-out in December 2014. During 2015, the operationalization of the procedure allowed for the identification of some practical difficulties (e.g., application to all diplomas or just research Masters and PhDs; issues about application of specific processes), which led to another round of revisions, culminating in the March 2016 version of the procedure. In February 2017, the procedure was launched in an online format (using the LimeSurvey platform) to facilitate completion of the questionnaire by jury members.

Both the Procedure and the associated Declaration of Interest form have been circulated to all professors, program directors, and administrative staff in the School of Public Health, and are also to be sent by supervisors (who are responsible for soliciting participation in juries) to all selected jury members during the process of forming a jury for their Masters or PhD students.

The aim of this Commentary is to share with the wider academic community a model for a practical procedure that could be used/adapted by other academic institutions to help more effectively manage the COI that are inherent in academe, specifically those that arise in the formation of Masters and PhD thesis juries.

The Procedure

Entitled *Procedure for Managing Conflicts of Interest when Constituting Masters and Doctoral Thesis Juries in the ÉSPUM*, the procedure is structured as follows: a ***Summary*** about the aims of identifying COI and the importance of their management; a ***Definition*** of COI, the one used by the University in its annual Declaration form; a list of pertinent ***Types*** of COI, adapted from a document produced by the University of Western Australia (11); a table of the ***Relations between jury members*** and the ***Process*** for forming the jury.

The official procedure is in French (Annex 1), but an English version is also made available to jury members and so is presented here, in Boxes, preceded or followed by text to briefly explain the content, structure, and reasoning behind the procedure and its associated declaration form.

Summary

- The management of conflicts of interest (COI) in the composition of Masters and PhD juries is essential in order to maintain the integrity and credibility of the jury process and the evaluation.
- Unaddressed COI bring with them important risks, namely bias/reduced objectivity in the evaluation process, but also a potential loss of trust by members of the academic community (internal and external to the ÉSPUM) in the institution and its processes, and in the quality of degree granted.
- It is thus essential that real and apparent COI be identified, so that they can then be evaluated (e.g., severity, nature of the risk involved) and thus managed appropriately.
- The starting point in a COI management process is to identify and be transparent about any real or apparent COI with the different potential jury members. It then becomes possible to determine whether disclosure of a COI is sufficient (in low-risk cases), or whether more strict interventions are required, such as not accepting certain potential jury members.

Starting in 2012, a concerted effort was made at the Université de Montréal to increase awareness about and build skills in addressing COI. One resource was the aforementioned website proving information about how to identify, evaluate and manage COI; another was the development of Application directives to explain how the top-level University COI policy should be implemented (e.g., Annual Declaration form). Nonetheless, it remains the case that despite these resources, COI is still poorly understood by members of the institution (e.g., students, administrative staff, professors). Thus, in developing the current procedure, attention was made to providing educational content to faculty and potential jury members about the nature and importance of dealing with COI appropriately.

Definition (see: www.interets.umontreal.ca)
A conflict of interest may arise when activities or situations place an individual or an organization in the presence of interests (personal, institutional or otherwise) that conflict with the interests inherent to the duties and responsibilities of their status or function. These interests include business interests, financial or nonfinancial (e.g., religious beliefs, values) relating to the organization or to the individual, their family members, friends or associates, past, present or future. These conflicts risk altering the integrity of the decisions made and so can cause harm and undermine public trust in the organization and its members.

The definition is the one developed for the University in 2012, and which is also included at the top of the Annual Declaration form.

Types of pertinent conflicts of interest to consider
Adapted from the "Conflict of Interest and Examiner Independence for Examination of Higher Degree by Research Thesis," Board of the Graduate Research School, University of Western Australia

The term 'Examiner' is understood to refer primarily to the external examiner of a PhD thesis and the internal jury member for a masters. The types of COI illustrated below are also relevant, but to a lesser degree, for the other members of the jury, such as the internal member (in the cases of a PhD), the President and the Dean's Representative (PhD). Note that the following list is aimed at helping to identify potentially problematic situations, so that they can then be evaluated and managed; it should not be read as a "check list" that leads to automatic exclusion of a jury member if one of the listed COI occurs. Cases of real or apparent COI need to be declared so that they can be evaluated and managed appropriately, when they cannot be avoided.

In the composition of a jury, an important concept is the notion of "critical distance" between the various jury members and the student/supervisor, and relative to the respective roles of the

members (e.g., president, internal or external jury members). For example, while it would be expected that the external examinee in a PhD defense would, with few exceptions, have little or no recent collaborations with the student or their supervisor, such a requirement could be difficult to achieve (e.g., lack of expertise) and unreasonable for a jury member (often a colleague) for the evaluation of a master's thesis. That being the case, other members of the jury, e.g., the president (also often a colleague), could be chosen who have less close relations with the student/supervisor, to help ensure the necessary critical distance.

Even if as professors we may think that we can be completely objective in the evaluation of a student's work, regardless of our relationship with the student, there is good empirical evidence that this is often not the case; it is difficult to recognize one's own interests and biases. Furthermore, the perception by third parties that there is a COI can significantly undermine the credibility of and trust in the evaluation process. It is thus essential to ensure that the different members of the jury are transparent about their interests and relations and that a critical distance be maintained to ensure an expected degree of impartiality.

Based on practical considerations and following a reflection about the nature of the associated risks, a distinction was made between the requirements for the external examiner and those of other jury members. Specifically, if all jury members, with the exception of the supervisor of course, are required to have no COI whatsoever, regardless of the risk, then it becomes almost impossible to constitute a jury. The notion of "critical distance" was thus introduced to highlight the importance of ensuring the most objective evaluation possible of the thesis, within reason; depending on the different roles of jury members, different levels or degrees of critical distance are necessary.

Critical distance is a means of pointing to widely shared ideals of objectivity and impartiality in academe, while accepting that professors are still human beings and so are nonetheless inextricably subjective, even if when they have PhDs! Evaluations and judgments will never be perfectly impartial, but one can still aim towards impartiality as an ideal (while also recognizing that it is ultimately unattainable). Humility and reflexivity are required, as well as the recognition that certain relations will make impartial judgments all the more difficult. In cases where there are relatively close relationships between students and jury members, such as between a student and their supervisor, it is unreasonable to expect a high degree of impartiality, so the expected critical distance will be less. A supervisor may (will) often have a direct interest in seeing their student succeed, i.e., a COI, and so a source of bias. They may legitimately defend their student's thesis while trying to give a fair judgment of the quality of the work, but it is unreasonable to expect them to be as impartial or have the same critical distance as other jury members. By contrast, when the jury member is essentially a stranger (e.g., a distant colleague with no history of collaboration) to the student and their supervisor, then one can reasonably expect a high degree of impartiality and thus maximal critical distance.

In recognizing that in a thesis jury there are different roles and responsibilities — e.g., president, supervisor, internal and external examiners — I argue that it is reasonable to accept different degrees of critical distance. To offset to some extent the biases that may result from COI generated by various sorts of relationships, I propose various thresholds of "critical distance" for the different roles in the jury (see the table in the section on **PhD Jury Composition**, below). In this view, expectations for impartiality for jury members will generally flow from least to most critical distance — supervisor (least), president, internal jury member, external evaluator (most) — but can be modulated depending on particular types of COI (a risk analysis), issues of availability of expertise, etc. So it may be legitimate

to accept an external evaluator who has also been a collaborator (but not too close) with the student student/supervisor, when 1) there are no other qualified evaluators available, and 2) other members, such as the president and internal jury member, are maximally critically distant. The goal is to create a jury that is as impartial as possible in order to ensure a fair review of the thesis, and if not all COI can be eliminated, then those that are tolerable can be counter-balanced.

To help the users of this procedure ask themselves the right questions in order to identify different types of COI, a list of potentially problematic COI was provided, grouped into *Work*, *Personal* and *Business* relations, as they pertain to any relations between the examiner (i.e., the jury members) and the student or the supervisor.

(A) Conflict with Student	
Category	**Type of COI**
Working relationship	• Examiner has co-authored a paper with the student • Examiner has worked with the student on matters of analysis • Examiner has worked with the student on matters of synthesis • Examiner has provided funds to the student • Examiner has employed or been employed by the student • Examiner is in negotiation to directly employ or be employed by the student • Examiner has acted as a referee for the student for employment
Personal Relationship	• Examiner is a known relative of the student • Examiner is a friend / associate / mentor of the student • Examiner has a personal relationship of enmity with the student • Examiner and the student have an existing or a previous emotional relationship, are coresidents or are members of a common household
Business Relationship	• Examiner is in a business relationship (past or present), such as partner in a small business or employment, with the student • Examiner is in a professional relationship, such as shared membership of a Board Committee, with the student • Examiner is in a social relationship with the student, such as co-Trustees of a Will, godparent, and miscellaneous personal contacts which give rise to the perception that the examiner may be dealing with the student in a less than objective manner

(B) Conflict with Supervisor	
Category	**Type of COI**
Working relationship	• Examiner has co-authored a publication with the supervisor in the past 3 years. Note: mitigating circumstances may exist in that co-authorship may be less than significant (i.e., one of many authors on a large group project). Such circumstances may not be considered as a conflict of interest but must be declared. • Examiner was a student of the supervisor within the past five years • Examiner holds a current grant with the supervisor. Note: Mitigating circumstances may exist (such as in first bullet), which should be declared. • Examiner has co-supervised with the supervisor in the past five years • Examiner holds a patent with the supervisor • Examiner had directly employed or was employed by the supervisor in the past five years
Personal Relationship	• Examiner is in negotiation to directly employ or be employed by the supervisor • Examiner is a relative of the supervisor • Examiner has a personal relationship of enmity with the supervisor • Examiner and the supervisor have an existing or a previous emotional relationship, are co-residents or are members of a common household

Business Relationship	• Examiner is in a business relationship (past or present), such as partner in a small business or employment, with the supervisor • Examiner has a current professional relationship, such as shared membership of a Board or Committee (including editorial and grant decision boards), with the supervisor. Note: Relationship should be declared in all circumstances. • Examiner is in a social relationship with the supervisor, such as co-Trustees of a Will, god-parent, and miscellaneous personal contacts which give rise to the perception that the examiner may be dealing with the supervisor in a less than objective manner

The issue of co-authorship and other research collaborations amongst jury members was one of the instigating factors for developing a more nuanced procedure. The choice of 3 years for co-authorship and 5 years for supervision were somewhat arbitrary but aimed at creating critical distance without undue constraint. Examiners found to be in one of these relations would not be automatically excluded; instead, the goal was to ensure declaration and documentation so as to enable an evaluation of their nature. For example, was the co-authorship a rare collaboration or part of a large team publication, where the examiner and supervisor had little in the way of real ongoing collaborations? Further, it was recognized that internal jury members (e.g., colleagues in the same Department or research centre) would more likely have collaborations, but these too should be disclosed so their nature could be evaluated, and not grounds for immediate exclusion.

(C) Conflict with the Subject Matter	
Category	**Type of COI**
Publication	• Examiner has published work critical or laudatory of the student's approach (naming the student / supervisor)
Public Forum	• Examiner has spoken publicly in a critical or laudatory way about the student's work (naming the student / supervisor)
Research	• Examiner has a direct commercial interest in the outcomes of the research

This section sought to bring attention to COI related to the subject matter of the student's work, particularly with regards to possible ideological COI that might lead to bias either in favour of or against the student and the evaluation of the content of the thesis.

PhD Jury Composition
Summary of the relations between jury members and the critical distance necessary to appropriately manage COI (with regards to the types of COI mentioned above).

Member/Role	**Relationship with student**	**Relationship with supervisor(s)**	**Critical distance**
President	• May have been a professor	• Often a colleague	• Must be sufficiently distant from student and supervisor to ensure a neutral process
Supervisor(s)	• Close relation with student	• NA	• Try to be as objective as possible in the evaluation process
Jury member (internal)	• May have been professor	• Often a colleague	• Must be sufficiently distant from student and supervisor to ensure a neutral process
External evaluator	• Should not be in a close relationship	• Should not be in a close relationship	• Must be external to the university • Must be an expert in the subject matter • Must be free from real or apparent COI

Dean's representative	• May have been a professor	• Should be from another department	• Guarantor of the quality and rigour of the exam process • Does not have to be a content expert

This table provides a summary of the roles and relationships between the different members of the jury, and the required (and realistic) critical distance that should be sought. It recognizes, for example, that the supervisor and the student will invariably have a close working relationship and so while the supervisor can evaluate their student, they are not impartial. By contrast the other jury members are held to a greater degree of critical distance.

PhD jury nomination process

Supervisor

1. The student's supervisor is responsible for creating a list of potential jury members, i.e., two people for each of the 3 categories of jury member: president, internal and external jury members:
   - Ensure the greatest possible critical distance on the part of all potential jury members;
   - Identify any real or apparent COI between the potential jury members, the supervisor and the student. To do so, completes the *Declaration of conflicts of interest* form;
   - If the COI appear inevitable, whether or not they are acceptable, the supervisor must document these on the form for selecting jury members;
   - Ensures the availability of the first choice of candidates (i.e., president, internal and external jury members);
2. Submits the candidate list and the *Declaration of conflicts of interest* form to the director of the option or of the program, in the case of programs without options.

Option or program director

3. The option or program director decides on the competence of candidates and the absence or presence of COI and, where applicable, the risks and their acceptability;
   - In the event that one or more candidates is not appropriate (e.g., because of expertise, unacceptable COI), the option or program director returns to the supervisor who recruits new candidates.
4. Where candidates are found to be appropriate, the director of the option informs the program director who chooses one candidate per category of jury member; in programs without a director for the option, the program director is responsible for evaluating the supervisor's proposals for forming the jury.
5. The graduate secretary asks the selected jury members (president, internal and external jury members) to complete the Declaration of conflicts of interest form
   - In the event that one or more candidates is not appropriate (e.g., because of expertise, unacceptable COI), the option or program director choses one of the other potential jury members. He/she may also return to the supervisor to recruit new candidates.
6. The jury nomination form is completed by the program director and submitted for signature to the Faculty superiors (Vice-Dean of Education).
7. The graduate secretary informs the selected jury members.
8. The jury processes can begin.

The decision to make the supervisor responsible for providing a list of potential jury members was again based both on pragmatic considerations and an evaluation of the risks or costs associated with other options, such as requiring the Option or Program director to make the selection. Most often, it is the supervisor who best knows the experts in the field who would be best placed to participate in jury. But to avoid obviously unethical situations where supervisors "stack the jury" with their friends to ensure an easy evaluation, the supervisor must provide a primary and secondary list of choices for each of position in the jury

(President, Internal Jury Member, External Evaluator, Dean's Representative), and also disclose any potential COI with these members. This disclosure is then verified by the Option or Program director, and then also cross-referenced with the Declarations of the selected jury members.

Masters Jury Composition			
Member/Role	**Relationship with student**	**Relationship with supervisor(s)**	**Critical distance**
President	• May have been a professor	• Often a colleague	• Must be sufficiently distant from student and supervisor to ensure a neutral process
Supervisor(s)	• Close relation with student	• NA	• Try to be as objective as possible in the evaluation process
Jury member (internal)	• May have been a professor	• Often a colleague	• Must be sufficiently distant from student and supervisor to ensure a neutral process
Masters jury nomination process • For a Masters with thesis, see the criteria and procedure for the PhD and adapt accordingly. • For a Masters with internship or directed study, even if the procedure is not directly applicable, the general principles aiming to minimize COI remain pertinent.			

The PhD procedure was adapted for the research Masters, which do not include an external evaluator or Dean's representative. The professional Masters programs do not involve a formal jury but instead rely on one or more evaluators (usually a colleague) to grade the student's final project (a report varying between 25-50 pages). Nonetheless, the general principles outlined in the procedure still apply.

Declaration of Conflicts of Interest Form

The *Declaration of conflicts of interest* forms (Annex 2), one for the supervisor and another for the jury members, have both a practical and psychological purpose: they both provide means to document real or potential COI so that they can be evaluated in the formation of a jury, and enable supervisors and potential jury members to reflect on their own COI and how these can be best managed.

The forms begin with the statement that "The purpose of this form is to provide information on the interests of potential jury members that could affect the evaluation process in the context of masters or doctoral juries" and then presents the Definition of COI described above, in the Procedure.

The supervisor and the potential jury members are asked to provide personal information (name and affiliation), and identify their role on the jury (president, supervisor, internal or external jury member, Dean's representative). They are then asked to fill in a table declaring all potential or real COI (based on the more detailed content outlined in the Procedure) and add any other COI that were not mentioned in the table.

For the supervisor:

Conflict of interest relative to your role as jury member Declare all personal, professional or financial relations with the jury members (President, Internal Jury Member, External Evaluator, Dean's Representative) that could be perceived to have an influence on the jury members. *(please check and provide any explanations)*					
Type of relation	**President**	**Internal jury member**	**External evaluator**	**Dean's representative**	**Comments**
Working relations • co-authored a paper in the last 3 years • hold a grant with … • was a student of … in the past five years • employed or has been employed by ... • is negotiating to directly employ or be employed by ... • acted as a reference for a job application					
Personal relations • is a family member • is a friend / partner / mentor • has a hostile personal relationship • has an existing or previous emotional connection, is coresident or a member of the same household					
Business relations • are in a business relationship (past or present), as a partner in • a small business or employment • has a current working relationship, such as membership of a board or committee • is in a social relationship, such as co-administration of a will, sponsor, or through various personal contacts					

For the jury members:

Conflict of interest relative to your role as jury member Declare all personal, professional or financial relations with the student or the supervisor that could be perceived to influence your roles as an examiner. (*please check and provide any explanations)* **<u>Relations with the student or supervisor(s)</u>**

Type of relation	With the student	With the supervisor	Comments
Working relations • co-authored a paper in the last 3 years • worked with the student on issues of analysis or synthesis • was a student of the supervisor in the last five years • provided funding for the student or holds a grant with the supervisor • employed or has been employed by... • is negotiating to directly employ or be employed by... • acted as a reference for a job			
Personal relations • is a family member • is a friend / partner / student mentor • has a hostile personal relationship • has an existing or previous emotional connection, is co-resident or a member of the same			
Business relations • are in a business relationship (past or present), as a partner in a small business or employment • has a current working relationship, such as membership of a board or committee • is in a social relationship, such as co-administration of a will, sponsor, or through various personal contacts			
<u>Relations with the research subject</u>			
Type of relation	**Yes/No**	**Comments**	
Publications • has published work critical or laudatory of the student's approach (naming the student / supervisor)			
Public forum • has spoken publicly in a fashion that is critical or laudatory of the student's work (naming the student / supervisor)			
Research • has a direct commercial interest in the research results			

Conclusion

Participating in the development of a practical procedure for managing COI in the composition of Masters and PhD juries at the School of Public Health proved to be a very rewarding experience. In the space of a few months (and then validated over a period of 2 years), I was able to put into practical application the results of almost a decade's worth of ethics research on university COI, that was primarily focused on documenting and raising awareness about the problem, i.e., that COI are widespread in academia, can be very problematic if left unaddressed, but that they can be managed with the right tools. In building such a COI management procedure, I was able help my colleagues address a real-world ethical problem in their role as supervisors, potential jury members and program directors. As with any new policy or procedure, it will take time and sustained effort to create awareness about both the procedure and the importance of implementing it in practice. Nor are procedures a panacea; there will be unintentional mistakes, important COI may not be disclosed, and some people may even wilfully ignore the procedure, thinking it irrelevant ("What do you mean I'm not objective? I'm a university professor!"). Surveillance by

secretaries (reminding supervisors and jury members to complete the forms), program directors, and the Vice-Dean will be important to ensuring compliance with the COI procedure and thus its effective integration into the practice of forming thesis juries.

What is important, in the end, is recognizing that good (i.e., practical and pertinent), procedures can be developed and implemented to support and encourage ethical conduct, and this includes the management of an issue as sensitive and as widely misunderstood as conflicts of interest (12).

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Annex 1

Mars 2016

Procédure de gestion des conflits d'intérêts dans la constitution des jurys de maîtrise et de doctorat à l'ÉSPUM

Résumé

- La gestion des conflits d'intérêts dans la composition des jurys de mémoire et de thèse est essentielle afin de maintenir l'intégrité et la crédibilité du jury et du processus d'évaluation.
- Les conflits d'intérêts non gérés apportent des risques importants, à savoir un biais ou une objectivité réduite dans le processus d'évaluation, mais également une perte potentielle de confiance par les membres de la communauté universitaire (internes et externes à l'ÉSPUM) dans l'institution et ses processus, et la qualité du diplôme décerné.
- Il est donc essentiel que les conflits d'intérêts réels et apparents soient identifiés, afin qu'ils puissent ensuite être évalués (ex. : la gravité, la nature du risque encouru) et donc gérés de façon appropriée.
- Le point de départ d'un processus de gestion des conflits d'intérêts est d'identifier et de faire preuve de transparence au sujet de tout conflit d'intérêts réel ou apparent avec les différents membres potentiels du jury. Il devient alors possible de déterminer si la déclaration d'un conflit d'intérêts est suffisante (dans les cas à faible risque), ou si les interventions plus strictes sont nécessaires, comme de ne pas accepter certains membres potentiels du jury.

Définition (voir : www.interets.umontreal.ca)

Un conflit d'intérêts peut survenir quand des activités ou des situations placent un individu ou une organisation en présence d'intérêts (personnels, institutionnels ou autres) qui entrent en conflit avec les intérêts inhérents aux devoirs et responsabilités liés à son statut ou à sa fonction. Ces intérêts comprennent notamment des intérêts commerciaux, financiers ou non pécuniaires (ex. : croyances religieuses, valeurs) se rapportant à l'organisation ou à l'individu, aux membres de sa famille, à ses amis ou à ses associés, anciens, actuels ou futurs. Ces conflits risquent d'altérer l'intégrité des décisions prises et ainsi de causer des torts et de compromettre la confiance du public à l'endroit de l'organisation et de ses membres.

Types de conflits d'intérêts pertinents à prendre en considération

Adapté de la « Conflict of Interest and Examiner Independence for Examination of Higher Degree by Research Thesis », Board of the Graduate Research School, University of Western Australia

Par « Examinateur », on entend *principalement* l'examinateur externe dans le cas d'une thèse ou le membre du jury dans un mémoire de recherche. Les types de conflits d'intérêts illustrés ci-bas sont également pertinents, mais à un degré moindre, pour d'autres membres du jury, tels qu'un membre interne (dans le cas d'une thèse), le président et le représentant du Doyen (thèse). Noter que la liste qui suit est destinée à aider à l'identification des situations potentiellement problématiques, afin qu'elles puissent ensuite être évaluées et gérées ; elle ne devrait pas être lue comme une liste à cocher « check list » qui mène à l'exclusion automatique d'un membre du jury si l'un des conflits d'intérêts énumérés se produit. Des cas de conflits d'intérêts réels ou apparents doivent être déclarés afin qu'ils puissent être évalués et gérés de façon appropriée, quand ils ne peuvent pas être évités.

Dans la constitution d'un jury, un concept important est la notion de « distance critique » entre les divers membres du jury et le candidat/directeur, et relativement au rôle respectif des membres (ex. : président, membre interne ou externe). Par exemple, lors d'une soutenance doctorale, il serait attendu que l'examinateur externe, à de rares exceptions près, n'ait pas ou peu de collaborations récentes avec le candidat ou le directeur ; il se peut qu'une telle exigence soit difficile à respecter (ex. : expertise rare) ou non raisonnable quand il s'agit d'un membre du jury (souvent un collègue) pour l'évaluation d'un mémoire de maîtrise. Dans ce cas, on peut s'assurer que les autres membres du jury n'aient pas ou peu de relations étroites avec le candidat/directeur afin d'assurer la distance critique nécessaire.

Même si, en tant que professeurs, nous croyons avoir l'objectivité requise pour évaluer un travail étudiant, peu importe notre relation avec ce dernier, il existe des données empiriques pour illustrer que ce n'est souvent pas le cas ; il peut être difficile de reconnaître ses intérêts et biais. De plus, une perception extérieure de l'existence de conflits d'intérêts peut entacher la crédibilité ou la confiance dans le processus. Il est donc essentiel de s'assurer que les différents membres du jury soient transparents en ce qui concerne leurs intérêts et relations et qu'une distance critique soit maintenue pour assurer le degré attendu d'impartialité.

(A) Conflits avec l'étudiant

Catégorie	**Type de conflit d'intérêts**
Relations de travail	• l'examinateur a coécrit un article avec l'étudiant • l'examinateur a travaillé avec l'étudiant sur des questions d'analyse • l'examinateur a travaillé avec l'étudiant sur les questions de synthèse • l'examinateur a fourni des fonds pour l'étudiant • l'examinateur a employé ou a été employé par l'étudiant • l'examinateur est en négociation pour employer directement ou être employé par l'étudiant • l'examinateur a agi comme référence pour l'étudiant pour un emploi
Relations personnelles	• l'examinateur est un membre de la famille de l'étudiant • l'examinateur est un ami / associé / mentor de l'étudiant • l'examinateur a une relation personnelle d'hostilité avec l'étudiant • l'examinateur et l'étudiant ont un lien affectif existant ou antérieur, sont corésidents ou sont membres d'un ménage commun
Relations d'affaires	• l'examinateur est dans une relation d'affaires (passée ou présente), avec l'étudiant, comme partenaire dans une petite entreprise ou d'emploi • l'examinateur est dans une relation professionnelle avec l'étudiant, telle que l'appartenance commune à un comité du conseil • l'examinateur est dans une relation sociale avec l'étudiant, comme coadministration d'un testament, parrain, ou par divers contacts personnels qui donnent lieu à la perception que l'examinateur peut agir d'une manière moins objective

(B) Conflits avec le superviseur

Catégorie	Type de conflit d'intérêts
Relations de travail	• l'examinateur est coauteur d'une publication avec le superviseur dans les 3 dernières années. Remarque: des circonstances atténuantes peuvent exister et la copaternité peut être moins importante (un des nombreux auteurs sur un grand projet d'équipe). De telles circonstances peuvent ne pas être considérées comme un conflit d'intérêts, mais doivent être déclarées. • l'examinateur était un étudiant du superviseur au cours des cinq dernières années • l'examinateur est titulaire d'une subvention actuelle avec le superviseur. Remarque: Il peut exister des circonstances atténuantes (voir ci-haut) qui doivent être déclarées. • l'examinateur a codirigé avec le superviseur au cours des cinq dernières années • l'examinateur est titulaire d'un brevet avec le superviseur • l'examinateur avait employé directement ou a été employé par le superviseur au cours des cinq dernières années
Relations personnelles	• l'examinateur est en négociation pour employer ou être employé par le superviseur • l'examinateur est un parent du superviseur • l'examinateur a une relation personnelle d'hostilité avec le superviseur • l'examinateur et le superviseur ont une relation émotionnelle existante ou antérieure, sont corésidents ou sont membres d'un ménage commun
Relations d'affaires	• l'examinateur est dans une relation d'affaires avec le superviseur (passée ou présente), comme partenaire dans une petite entreprise ou d'emploi, • l'examinateur a une relation professionnelle actuelle avec le superviseur, tels que l'appartenance à un conseil d'administration ou comité (y compris des comités de rédaction et de subvention). Remarque: La relation doit être déclarée en toutes circonstances • l'examinateur est dans une relation sociale avec le superviseur, comme coadministration d'un testament, parrain, ou par des contacts personnels divers qui donnent lieu à la perception que l'examinateur peut agir d'une manière moins objective

(C) Conflits avec l'objet / sujet de recherche

Catégorie	Type de conflit d'intérêts
Publication	• l'examinateur a publié des travaux critiques ou louangeurs de l'approche de l'étudiant en nommant l'étudiant ou le superviseur.
Forum public	• l'examinateur a critiqué ou louangé publiquement le travail de l'étudiant en nommant l'étudiant ou le superviseur.
Recherche	• l'examinateur a un intérêt commercial direct dans les résultats de la recherche

Composition d'un jury de thèse

Résumé des relations entre les membres du jury, et la distance critique nécessaire pour bien gérer les conflits d'intérêts (en référence aux types de conflits d'intérêts mentionnés ci-dessus).

Membre / Rôle	Relations avec l'étudiant	Relation avec le(s) directeur(s)	Distance critique
Président	• Peut avoir été un professeur	• Souvent un collègue	• Doit être suffisamment éloigné de l'étudiant et du superviseur pour assurer une procédure neutre
Superviseur(s)	• Relation très proche avec l'étudiant	• NA	• Essayez d'être aussi objectif que possible dans le processus d'évaluation

Membre du jury (interne)	• Peut avoir été un professeur	• Souvent un collègue	• Doit être suffisamment éloigné de l'étudiant et du superviseur pour assurer une procédure neutre
Évaluateur externe	• Ne doit pas être dans une relation de proximité	• Ne doit pas être dans une relation de proximité	• Doit être à l'extérieur de l'université • Doit être expert dans la matière • Doit être exempt de conflits d'intérêts réels ou apparents
Représentant du doyen	• Peut avoir été professeur	• Devrait être d'un autre département	• Garant de la qualité et de la rigueur du processus d'examen • Ne doit pas être un expert dans la matière

Processus de nomination de jury de thèse

Directeur de recherche

1) Le directeur de recherche de l'étudiant est responsable de la constitution d'une liste de membres potentiels du jury, i.e., deux personnes pour chacune des 3 catégories de membre du jury : président, membre interne et membre externe :
   - Il doit assurer la plus grande distance critique possible de la part de tous les membres potentiels du jury ;
   - Il doit identifier tout conflit d'intérêts réel ou apparent entre les membres du jury potentiels, le directeur de recherche et l'étudiant. Pour ce faire, il remplit un formulaire de *déclaration de conflits d'intérêts* ;
   - Si les conflits d'intérêts apparaissent inévitables, acceptables ou non, le directeur de recherche doit les documenter sur le formulaire de sélection des membres du jury ;
   - Il s'assure de la disponibilité du premier choix de candidats (i.e., président, membre interne et externe) ;

2) Il soumet ces candidatures et son formulaire de *déclaration de conflits d'intérêts* au responsable d'option ou au directeur de programme, dans le cas des programmes sans responsable d'option.

Responsable d'option / directeur du programme

3) Le responsable d'option, ou le directeur de programme, se prononce sur la compétence des candidats et sur l'absence ou la présence de conflits d'intérêts et, le cas échéant, sur les risques qu'ils comportent et leur acceptabilité ou non ;
   - Dans la mesure où une ou des candidatures ne sont pas conformes (ex. : question d'expertise, conflit d'intérêts inacceptable), le responsable d'option ou le directeur de programme retourne auprès du directeur de recherche qui recrute de nouveaux candidats.

4) Lorsque les candidatures sont jugées conformes, le responsable d'option informe le directeur du programme des candidats retenus par catégorie de membres du jury. Dans les programmes sans responsable d'option, le directeur de programme prend la responsabilité d'évaluer les propositions du directeur de recherche pour constituer le jury.

5) La TGDE demande aux membres du jury présélectionnés (président, membres interne et externe) de remplir le formulaire de *déclaration de conflits d'intérêts*.
   - Dans la mesure où une ou des candidatures ne sont pas conformes (ex. : question d'expertise, conflits d'intérêts inacceptables), le responsable d'option ou le

directeur de programme choisit un des autres membres du jury potentiels. Il peut également retourner auprès du directeur de recherche pour recruter de nouveaux candidats.

6) Le formulaire de nomination du jury est complété par le directeur de programme et soumis pour signature aux responsables facultaires (Vice-décanat études).
7) La Technicienne en gestion des dossiers étudiants (TGDE) informe les membres de jury sélectionnés.
8) Les procédures d'examen peuvent alors s'enclencher.

Composition d'un jury de maîtrise

Membre / Rôle	**Relations avec l'étudiant**	**Relation avec le(s) directeur(s)**	**Distance critique**
Président	• Peut avoir été un professeur	• Souvent un collègue	• Doit être suffisamment éloigné de l'étudiant et du superviseur pour assurer une procédure neutre
Superviseur(s)	• Relation très proche avec l'étudiant	• NA	• Essayer d'être aussi objectif que possible dans le processus d'évaluation
Membre du jury (interne)	• Peut avoir été un professeur	• Souvent un collègue	• Doit être suffisamment éloigné de l'étudiant et du superviseur pour assurer une procédure neutre

Processus de nomination de jury de maitrise

- Pour la maitrise avec mémoire, voir les critères et processus pour le doctorat et adapter en conséquence.
- Pour la maitrise avec stage ou travail dirigé, même si le processus n'est pas directement applicable, les principes généraux visant à minimiser les conflits d'intérêts restent pertinents.

Annex 2

Déclaration de conflits d'intérêts — jurys de maitrise/doctorat *Superviseur*

Le but de ce formulaire est de fournir de l'information sur les intérêts des membres potentiels de jury qui pourraient influer sur le processus d'évaluation dans le contexte d'un jury de maîtrise ou de doctorat.

Définition (voir : www.interets.umontreal.ca)
Un conflit d'intérêts peut survenir quand des activités ou des situations placent un individu ou une organisation en présence d'intérêts (personnels, institutionnels ou autres) qui entrent en conflit avec les intérêts inhérents aux devoirs et responsabilités liés à son statut ou à sa fonction. Ces intérêts comprennent notamment des intérêts commerciaux, financiers ou non pécuniaires (ex. : croyances religieuses, valeurs) se rapportant à l'organisation ou à l'individu, aux membres de sa famille, à ses amis ou à ses associés, anciens, actuels ou futurs. Ces conflits risquent d'altérer l'intégrité des décisions prises et ainsi de causer des torts et de compromettre la confiance du public à l'endroit de l'organisation et de ses membres.

1) Étudiant(e)
Nom: Programme : Option :

2) Superviseur
Nom: Affiliation institutionnelle :

Superviseur principal : Co-superviseur :

Rôle (svp cocher un):

Président	Superviseur(s)	Membre du jury (interne)	Évaluateur externe	Représentant du doyen

3) Conflits d'intérêts en relation avec les membres du jury
Déclarer toutes les relations personnelles, professionnelles ou financières avec les membres du jury (président, membre du jury interne, évaluateur externe, représentant du doyen) qui pourraient être perçues comme ayant une influence sur les membres du jury. *(svp, cocher et fournir des explications)*

Type de relation	**Président**	**Membre du jury interne**	**Évaluateur externe**	**Représentant du doyen**	**Commentaires**
Relations de travail • a coécrit un papier dans les 3 dernières années • est titulaire d'une subvention avec… • était un étudiant avec… au cours des cinq années • a employé ou a été employé par… • est en négociation pour employer directement ou être employé par… • a agi comme référence pour un emploi					

Relations personnelles • est un membre de la famille • est un ami / associé / mentor • a une relation personnelle d'hostilité • a un lien affectif existant ou antérieur, est corésident ou membre d'un ménage commun					
Relations d'affaires • est dans une relation d'affaires (passée ou présente), comme partenaire dans une petite entreprise ou d'emploi • a une relation professionnelle actuelle, telle que l'appartenance à un conseil d'administration ou comité • est dans une relation sociale, comme coadministration d'un testament, parrain, ou par des contacts personnels divers					

4) Autres relations

Déclarer toutes autres relations ou activités qui pourraient être perçues comme ayant influencé, ou qui donnent l'apparence d'influencer l'objectivité ou impartialité des membres de jury.

☐ Aucun autre lien, condition ou circonstance présentant un risque de conflit d'intérêts

☐ Oui, les relations, conditions ou circonstances suivantes sont présentes (expliquer ci-dessous):

Nom _____Date _____

Déclaration de conflits d'intérêts — jurys de maitrise/doctorat

Membres du jury

Le but de ce formulaire est de fournir de l'information sur les intérêts des membres potentiels de jury qui pourraient influer sur le processus d'évaluation dans le contexte d'un jury de maitrise ou de doctorat.

Définition (voir : www.interets.umontreal.ca)
Un conflit d'intérêts peut survenir quand des activités ou des situations placent un individu ou une organisation en présence d'intérêts (personnels, institutionnels ou autres) qui entrent en conflit avec les intérêts inhérents aux devoirs et responsabilités liés à son statut ou à sa fonction. Ces intérêts comprennent notamment des intérêts commerciaux, financiers ou non pécuniaires (ex. : croyances religieuses, valeurs) se rapportant à l'organisation ou à l'individu, aux membres de sa famille, à ses amis ou à ses associés, anciens, actuels ou futurs. Ces conflits risquent d'altérer l'intégrité des décisions prises et ainsi de causer des torts et de compromettre la confiance du public à l'endroit de l'organisation et de ses membres.

1) Jury

Nom de l'étudiant(e):	Nom(s) du/des superviseur(s) :

2) Information personnelle

Nom:	Affiliation institutionnelle :

Rôle (svp cocher un):

Président	Membre du jury (interne)	Évaluateur externe	Représentant du doyen

3) Conflits d'intérêts pertinent à votre rôle comme membre du jury

Déclarer toutes les relations personnelles, professionnelles ou financières avec l'étudiant ou le directeur qui pourraient être perçues comme ayant une influence sur votre rôle comme examinateur. *(svp, cocher et fournir des explications)*

3.1 Relations avec l'étudiant ou le(s) directeur(s)

Type de relation	**Avec l'étudiant**	**Avec le directeur**	**Commentaires**
Relations de travail • a coécrit un papier dans les 3 dernières années • a travaillé avec l'étudiant sur des questions d'analyse ou de synthèse • était un étudiant du superviseur au cours des cinq dernières années • a fourni des fonds pour l'étudiant ou est titulaire d'une subvention avec le superviseur • a employé ou a été employé par… • est en négociation pour employer directement ou être employé par… • a agi comme référence pour un emploi			

Relations personnelles • est un membre de la famille • est un ami / associé / mentor de l'étudiant • a une relation personnelle d'hostilité • a un lien affectif existant ou antérieur, est corésident ou membre d'un ménage commun			
Relations d'affaires • est dans une relation d'affaires (passée ou présente), comme partenaire dans une petite entreprise ou d'emploi • a une relation professionnelle actuelle, telle que l'appartenance à un conseil d'administration ou comité • est dans une relation sociale, comme coadministration d'un testament, parrain, ou par des contacts personnels divers			

3.2 Relations avec le sujet de recherche

Type de relation	**Oui/Non**	**Commentaires**
Publication • a publié des travaux critiques ou louangeurs de l'approche de l'étudiant (en nommant l'étudiant / superviseur)		
Forum public • a parlé publiquement de manière critique ou louangé sur le travail de l'étudiant (en nommant l'étudiant / superviseur)		
Recherche • a un intérêt commercial direct dans les résultats de la recherche		

4) Autres relations

Divulguer toutes autres relations ou activités qui pourraient être perçues comme ayant influencé, ou qui donnent l'apparence d'influencer votre objectivité ou impartialité en tant que membre de jury.

☐ Aucun autre lien, condition ou circonstance présentant un risque de conflit d'intérêts

☐ Oui, les relations, conditions ou circonstances suivantes sont présentes (expliquer ci-dessous):

Nom _____Date _____

Part 2. Research and Publication

Part 2 is focused on the multifaceted nature of COI in academic research and publication, and their prevalence across disciplines, institutional contexts, and professional roles. The case studies and articles explore how COI can arise from financial, institutional, ideological, and relational dynamics that affect researchers, research ethics boards, journal editors, public health advisors, and technology transfer officers. Highlighted are the ethical tensions that emerge when personal or institutional interests intersect with professional responsibilities, particularly in contexts involving vulnerable populations, industry partnerships, and public policy influence. COI are not inherently unethical but require transparent identification, proportional management, and institutional accountability. The texts critique overly rigid or opaque governance structures and advocate for a balanced approach that combines formal policies with education, reflexivity, and stakeholder engagement. Special attention is given to the risks of research misconduct, editorial bias, and erosion of public trust when COI are poorly managed or concealed.

Drawing on international examples and empirical research, practical tools and policy recommendations are proposed for managing COI in diverse academic settings. Systemic reforms are needed to support ethical decision-making, including clearer disclosure practices, improved ethics training, and more inclusive governance frameworks. In an increasingly complex and interconnected academic landscape, COI management must be seen as a cornerstone of research integrity and institutional credibility.

Case studies

- Research misconduct caused by self-interest: how to manage such a situation?
- Conflict of interest in university technology transfer
- Improving understanding and management of conflicts of interest among experts advising on public health decisions
- Integrity in research: resisting conflicts of interest, fraud, bribes and other forms of corruption in research
- Explain the potential conflicts of interest to which health care workers are exposed when participating in emergency research activities

Articles

- *Coalition Priorité Cancer* and the pharmaceutical industry in Quebec: Conflicts of interest influence in the reimbursement of expensive cancer drugs?
- Accessibility and transparency of editor conflicts of interest policy instruments in medical journals
- Barriers to research on research ethics review and conflicts of interest
- Managing antimicrobial resistance in food production: conflicts of interest and politics in the development of public health policy
- Identification and management of conflicts of interest: governance tools for the Observatory on the Quality of the Food Supply.

Case Studies

Research misconduct caused by self-interest: how to manage such a situation?

Hazar Haidar

Original version: Haidar H. L'inconduite en recherche engendrée par l'intérêt personnel: comment gérer une telle situation? BioéthiqueOnline. 2012;2(16).

Summary

This fictional case study illustrates how the results of certain research projects can be used in order to serve personal interests, leading to scientific research misconduct.

Introductory Note

It is important to first define some terms. By *primary research* we mean an approach aimed at the development of knowledge through a disciplined inquiry or systematic investigation (1). The term *scientific misconduct* involves any behavior or act that is contrary to scientific ethics, that is, the values, customs, duties and rules, whether tacit or formal, that are recognized by the scientific community or by wider society as governing the work and individual behavior of scientists (2). Misconduct not only results in harm to the general functioning of the scientific community, but it can in some cases infringe upon the fundamental rights of individuals, and even cause irreparable harm. Depending on the nature and severity of the behaviour, scientific misconduct can be organised into various categories: negligence, breach of individual rights, conflict of interest and scientific fraud (2).

The Case: Zahi the Anthropologist

Zahi, a young anthropologist and ethnobotanist in training, is a doctoral student at a Canadian university. For several years, he has worked on a project studying an indigenous population in South Africa. The interest of this project emerges from the particular longevity of the individuals within the study population: 3.6% of individuals are over 65 years of age (3) while in the Canadian population, the percentage is 14,9% (4). In addition, these people are healthy, are rarely affected by diseases and their faces do not show the aging traits normally observed in individuals from other populations of a comparable age.

Zahi began his fieldwork almost two years ago. His study is based mainly on participant observation in the population in order to better describe and understand their living environment and their interaction with it. To better understand the longevity of the individuals in this population, Zahi conducted fifteen interviews with people whose age was between 65 and 85 years. During his fieldwork, Zahi established good relations with the population. After analyzing the results of his research into the lifestyle, interaction with the environment and eating habits of this population, Zahi noticed that a specific common element was found in their diet. Indeed, during the interviews, participants talked about the process of picking a particular plant, its transformation and its frequent use in their diet. This observation, and Zahi's ethnobotanical skills, prompted him to "decipher the secrets of this plant." He discovered that it is a rare species of plant and unique to the island. Satisfied and proud of this discovery, he rushed to tell his supervisor, Professor Pierre. The latter, delighted by this news, asked his student to devote more time to the study and broaden the spectrum of his work, to include a larger number of participants in order to confirm his observations.

Professor Pierre tells Zahi that if his hypothesis is true, that is to say, that this plant plays a role in the longevity of individuals in the population, they might seek the help of one of his colleagues to perform a molecular and clinical study. Professor Pierre explains that, in the event that this promising plant contains an active molecule that can fight aging, they can take the opportunity to make some money and thus finance further research projects. Professor Pierre adds that after several years of research they will have a "pill" that would be a "blockbuster" and could generate millions of dollars each year. Shaken by the unexpected reaction of his supervisor, Zahi conceals his two major fears. The first is that the exploitation of this rare plant by the pharmaceutical industry will endanger the lifestyle of the population. The second and more important fear is about the population itself. Even if this plant can be grown in laboratories around the world, Zahi is concerned about the population being used as guinea pigs for experimental research, which would necessarily involve taking blood samples and conducting other necessary medical tests to prove the effect of this plant. He is also worried about the upheaval of their lifestyle and interference with their dietary traditions once the research begins. Further, the revelation of Professor Pierre about the use of the population's natural resources poses a dilemma for Zahi:

- Should he attempt to communicate his concerns with his professor? Should he talk about the plan to the Director of the Anthropology Department or the council of community leaders? Is it possible to ensure the inclusion of the population in the project so that they share in the long-term economic benefits?
- Or should he say nothing and follow the rules imposed by his professor, and participate in a project that could bring him wealth and fame as a researcher, but perhaps at the expense of the population?

Zahi is very anxious about the decision he must take and its consequences. If he decides to reveal the plan prepared by his professor, he risks losing the years of work spent on his thesis project, as happened with one of his colleagues in a similar situation. Zahi thus decides to discuss his concerns with his professor: he reveals that he must ensure that the population is not deprived of this plant and that they benefit from the results of the research, whether financial or otherwise. However, Professor Pierre bypasses the subject and implies that it is not his intention to include the population in any benefit sharing because he plans to bring the plant back to grow locally. Further, he asks Zahi to bring him a sample of the plant.

While Zahi recruits an increasing number of participants in the project and procures a sample of the plant, Professor Pierre contacts Professor Fawaz, one of his dermatologist colleagues — a researcher and founder of a small pharmaceutical company — to explain the situation. They come to an agreement to launch a study on the potential of this plant. They decide that Professor Fawaz will be responsible for the project, provided that he finances the clinical research part of the project; the molecular studies will be funded by the university. Professor Fawaz gives the project to his laboratory research team. The first step is to do an extraction to separate out the different molecules. After a few months, the team was able to identify the molecule carrying the active agent (5). Zahi, who is conducting his fieldwork, is still not aware of the progress of Professor Fawaz's project. The first in vitro molecular experimental studies enable an understanding of the mechanism of action of the active substance. "Eureka!", "A molecule unlike any other" affirms Professor Fawaz to Professor Pierre. The latter reveals his concern about the project's acceptance by the university research ethics board (REB), and the ability to obtain a larger supply of this plant in order to begin the clinical research; so Professor Fawaz convinces him to divide the tasks. Professor Pierre will be responsible for obtaining approval from the university REB but will not disclose his

financial conflict of interest: he will not mention that Professor Fawaz, the project manager, has a pharmaceutical company that is funding the clinical research part of the project. Professor Fawaz, for his part, confides to Professor Pierre that he is willing to pay bribes to members of the REB in Africa to encourage them to approve the project in the event of a refusal concerning the exploitation of the plant or a risk to the culture of the population, for example. The African REB members come from the dominant tribe and are not part of the community where the plant is located. Moreover, without declaring it to the REB, Professor Fawaz will pay the community to ensure easy access to the plant, which will constitute both a source of income for the local population and be an important discovery to advance research on aging.

Professor Pierre tells Zahi the news but hiding the key issues with regard to possible problems with the REBs, and the means he intends to use with the help of Professor Fawaz to ensure approval of their project. However, Zahi still feels guilty and helpless because his fear of jeopardizing his studies has led him away from his moral obligation to ensure that the population has an equal share of the profits from this research and is not used as guinea pigs.

Questions to Consider

1. In your opinion, how should Zahi behave in the face of this dilemma and how should it be managed?
    - In fact, Zahi's choice was to obey the orders of his professor to "save" his own interests: have his studies funded, gain notoriety and possibly even have his name on a patent. Is his behavior ethically justifiable?
    - What risks would he have to face, for example, if he had referred the issue to the Director of the Anthropology Department and the council of community leaders with whom he had established a relationship of trust during his years of field research?

2. Professor Pierre and his friend Professor Fawaz seem very interested in developing a blockbuster drug in order to make money and gain notoriety, to the point where the former is engaged in academic misconduct: he does not disclose his financial conflict of interest (COI) to the university REB; and the latter in corruption: Fawaz is ready to use of bribes to ensure approval by the African REB.
    - Non-disclosure to the REB of financial COI is a violation of the ethical conduct of research. How, in your opinion, should the REB handle the situation in the event that they discover the presence of these financial COI?
    - In the world of research, misconduct and corruption are problems that vary in scale and between countries (fraud, falsification of results, non-disclosure of the COI to the REB, bribes for international REB, etc.) (6,7). What are the possible solutions that you could suggest to address these problems?

3. The last part of the text reveals a certain situation that reflects some of the real-world and perilous challenges to which some REBs and research participants are exposed (e.g., bribes in the form of a wage increase for REB members in Africa and a risk of exhausting the natural wealth of the population without giving a fair share of any profits).
    - What are the risks envisaged for both the REB, for the research project and for the indigenous population?
    - What solutions can you suggest to avoid the possible financial influence on the REB's decisions, as well as those of the participants?

4. Research projects on indigenous peoples that do not appear to raise any ethical concerns have in the past found their results used in an unethical manner: for example, the use of the information reported by anthropologists by military personnel to facilitate military interests (8). Would such a concern be sufficient to prohibit research on these populations?
5. Considering that the proposed research and commercial application of the plant seem very promising:
    - Should Zahi ensure that the community is involved in the research and share in the benefits from its commercialization?
    - Does this represent an acceptable compromise?

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Suggested Readings

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Conflict of interest in university technology transfer

Ginette Mathieu

Original version: Mathieu G. Conflict of interest in university technology transfer. BioéthiqueOnline. 2012;1(16).

Summary

Conflicts of interest (COI) and commitment in universities are not only issues limited to university researchers; they may become issues for individuals' professional actions or decisions at the level of administrative staff. For example, people associated with technology transfer licensing also need to be alert to COI, and to ensure they take appropriate measures to meet their commitments and work in line with the interests of their employer (the University) and the researchers with whom they work.

Acknowledgements

I would like to thank Marie-Josée Potvin and Bryn Williams-Jones for their helpful remarks on this case study. Many of the ideas here have benefited from ongoing critique and discussion with the Conflict-of-Interest Research Group at the Université de Montréal. My studies were supported by a scholarship from the Centre interuniversitaire de recherche sur la science et la technologie (CIRST). This research was supported by grants to Williams-Jones from the Fonds de recherche du Québec — Société et culture (FRQ-SC) and the Ethics Office of Canadian Institutes of Health Research (CIHR).

This case study is inspired by a story of interest that occurred at the University of Texas at Austin in December 2011 (1). The individual and institution mentioned in this case study are fictional.

Background

Many US and Canadian universities host technology transfer offices (TTO), sometimes called technology licensing offices or university-research partnerships offices. These offices have been put in place to facilitate the translation of university research findings into commercial products (2). The development of TTOs has been supported over the past 30 years by both public and private incentives to encourage universities to be proactive in moving research findings from the laboratory to the marketplace, to stimulate university entrepreneurship and thus economic development.

In the United States, the Bayh-Dole Act, enacted in 1980, created a uniform patent policy among the many federal agencies that fund research, enabling small businesses and non-profit organizations, like universities, to retain title to inventions made under federally-funded research programs. Through such legislation, universities have an implicit obligation to collaborate with companies to commercialize research findings arising from federal funding (3). In Canada, federal and provincial governments, mainly through research funding agencies, have put in place numerous university-industry partnership programs to stimulate technology transfers at the industrial level (4,5).

TTOs act as intermediaries between industry, universities and researchers to assess the potential economic value of research findings, so that they can be translated into commercial products. While research findings may prove to have a potential economic value, they are

often unproven at the industrial level. Thus companies must often commit to investing further in both Research and Development (R&D) to bring university innovations to market.

The TTO may assist researchers in obtaining R&D funding support (e.g., from venture capital), negotiating research contracts and licences with funding agencies and industry, filing for patent protection, and seeking industrial financial support for further development (6). Instead of negotiating a licence agreement with an existing company, researchers might also prefer to launch start-up companies to develop an innovation because they want to be actively involved in moving it to market. In such a case, the TTO will work with the researcher and external venture capitalists in the creation of the start-up. License agreements between companies or start-ups are usually subject to upfront fees, royalties or milestone payments to the university (which vary depending on institutional intellectual property agreements). In the case of start-up companies, the university may even claim equity as recompense for their investment (i.e., the support of the TTO) and support of the researcher (i.e., the institutional research environment).

Administrative staff from the TTO must be technically trained, have good communication and negotiation skills, and act as "neutral" intermediaries between researchers and industry to protect the university's and researcher's intellectual property rights. It is common knowledge to people active in the TTO sector that they should pay attention to their institutional conflict of interest (COI) policy. Some US universities — such as Harvard University, the University of Minnesota and the University of North Carolina — have even implemented specific guidelines addressing the management of COI in technology transfer (7-9).

The Case

Eric has a PhD in mechanical engineering and is a full-time technology transfer officer in the Office for Technology Licensing and Industry Collaboration (OTLIC) at Lewiston University. Eric's activities include technical reviews, negotiating research agreements with industry partners, promoting University researchers' expertise and innovations to external enterprises, and facilitating the launch of start-up companies.

Over the past three years, Dr. Fennec — a professor in bioengineering at Lewiston — has benefited from important public funding from the National Science Funding Council to support some of his research, specifically in the field of battery longevity for active implantable medical devices (AIMD). Batteries are responsible for supplying electrical energy to such devices, and they have a current lifetime of 3 to 8 years. Patients benefiting from battery-powered implantable devices have to undergo multiple surgeries throughout their lives because of limited battery life. AIMD procedures are expensive and risky, so increasing the lifespan of implant batteries could provide important benefits both to patients (fewer surgical interventions) and to the health care system (cost savings). During the course of his research, Dr. Fennec developed a new power system that, according to preliminary findings, increases the battery lifespan of AIMD by 50%. If commercialized, Dr. Fennec anticipates that this technology could be a "game changer" by making these devices more patient-friendly, thereby increasing their application in clinical practice. This could also generate significant revenues and an excellent visibility for Lewiston University and for Dr. Fennec's research group.

Dr. Fennec sought to file a patent and a trademark for the technology he developed, called *TechLight*. According to the University Intellectual Property Policy, Dr. Fennec had to submit a patent disclosure to the OTLIC, and specifically to Eric who is the technology transfer officer

dedicated to working with faculty members in the biomedical sciences. After a technical review to evaluate the patentability and potential commercialization of the technology, Eric worked with an external patent agent to file a patent application under the international Patent Cooperation Treaty (PCT). The PCT procedure essentially leads to a standard national or regional patent application, which may be granted or rejected according to applicable national laws, in each jurisdiction in which a patent is desired.

Dr. Fennec has discussed with Eric his strong interest in creating a start-up (to be named *LightCo*) to commercialize *TechLight* because Dr. Fennec would like to keep control of the development of his technology. But Eric has some doubts about the "entrepreneurial capacities" of Dr. Fennec, who has absolutely no business expertise or experience working with entrepreneurs or venture capitalists. Eric anticipates that *TechLight* could be easily licensed to an already established medical device company. Nevertheless, Eric respects Dr. Fennec's determination to create his own start-up and proposes that they meet with a representative from *VenCo*, a venture capital firm with which the University usually works under a non-exclusive agreement. The aim would be to discuss arrangements to facilitate the creation of the start-up *LightCo*, to determine the best approach to obtaining the necessary leverage financing to cover initial operating costs and R&D expenses, and to develop a business plan that could then attract further venture capital support.

Dr. Fennec is concerned by a bad experience that one of his colleagues had with the venture capital firm *VenCo* and so he fears losing control of his start-up. Yet, he also recognises that he needs practical guidance in becoming an "academic entrepreneur", so he has suggested to Eric that they could instead work with *PatCo*, a for-profit consulting firm offering services to small and medium enterprises and start-ups. *PatCo* provides support in developing R&D programs, preparing business plans, searching for external funding, and recruiting professional expertise. In exchange for this technical and financial support, *PatCo* asks for up to 5% equity in their clients' business. Dr. Fennec mentions to Eric that he has already met with the scientific advisor of this firm.

Eric expresses concern over Dr. Fennec's initiative because his brother, William, is an active founding member of *PatCo* who deals with the firm's business matters, including intellectual property negotiations and company registration (10,11). Although Eric has no direct financial interest in the firm, he does not feel comfortable with the fact that Dr. Fennec first consulted with *PatCo* and so Eric raises the issue with him.

From Dr. Fennec's point of view, the fact that Eric has no direct interest in *PatCo* and will not profit directly from the commercialization of *TechLight* means that there is no problem. In his professional judgment, Eric thinks that *TechLight* could prove to be a real break-through in the field and is an innovation that has the potential to generate important revenues both for Dr. Fennec (via his spin-off, *LightCo*) and for Lewiston University. Eric wants to maintain good relations with Dr. Fennec and so works actively with him throughout the development of his start-up and the commercialization of *TechLight* in collaboration with *PatCo* — even if he feels not completely at ease working with his brother's firm. Eric has confirmed that according to the University's policies, provided that the University is compensated for Intellectual Property rights, it would be possible to initiate a technology transfer agreement for Dr. Fennec once the start-up has been created.

Questions to consider

1. What challenges does Eric face in meeting the expectations of both the University and its researchers?

2. Does Eric's professional interest in technology transfer (e.g., promotion) influence him to inappropriately value researchers' innovations primarily in terms of their commercial success?
    - Should technology transfer focus primarily on transforming researchers' findings into profitable outcomes
3. Once Eric has disclosed the potential conflict of interest involving his brother William, how should he deal with the issue? Should he have only disclosed the conflict to Dr. Fennec or to his superiors as well?
4. Is there a conflict between the role of the University as a research organization and that of becoming a commercial partner in innovations when the time comes to commercializing patents?
    - Could the technology transfer process in which Eric and Dr. Fennec are involved be blurring one of the primary missions of the University, that is, knowledge production?
5. How important is the possibility that Dr. Fennec, as an "academic entrepreneur", may have conflicting interests and responsibilities with his role as a "university researcher" and professor?
    - Does Eric have any responsibility to discuss or address these issues with Dr. Fennec?

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Improving understanding and management of conflicts of interest among experts advising on public health decisions

Cloutier A-I, Bélisle Pipon J-C, Ringuette L, Doudenkova V, Williams-Jones B.

Original version: Cloutier A-I, Bélisle Pipon J-C, Ringuette L, Doudenkova V, Williams-Jones B. Améliorer la compréhension et la gestion des conflits d'intérêts des experts conseillant la prise de décisions en santé publique. BioéthiqueOnline. 2016;5(38).

Summary

In Québec, in Canada and elsewhere in the world, expert advisory committees advise and guide government decision-makers in the choice of new drugs, vaccines to be used or interventions to be put in place. In parallel, these experts are receiving increasing support from private companies to conduct their research or to disseminate the results of their research. Such situations place them at risk of conflicts of interest and may eventually undermine confidence in public decision-making. This case study stimulates reflection into what constitutes sound and optimal management of conflict-of-interest situations by expert members and the organizations in which they have an advising role.

Acknowledgements

AIC would like to thank all the professors of the introductory course on the methodology of Human Sciences at Collège Jean-de-Brébeuf and, in particular, Étienne Roy and Sébastien Bureau who, through their dedication, made the realisation of the internship possible as a part of this course. JCBP is supported by a Doctoral Fellowship from the Fonds de recherche du Québec — Santé (FRQ-S) & the Québec SPOR-SUPPORT Unit.

Introduction

Given its importance, public decision-making must be based on the best available knowledge. In Quebec, since the introduction of the Public Health Act in 2002, decisions must be evidence-based (1). Rigorous and transparent analysis of this evidence enables effective interventions to be put in place, resources to be managed in a structured way and, overall, helps to ensure better results in terms of population health interventions (2).

The leaders of public institutions often call on expert consultants to base their decisions on evidence. Their role is to give their opinions on various public health issues, including immunisation (e.g., the Comité sur l'immunisation du Québec, CIQ) (3). They are called upon to advise various levels of decision-making and are generally grouped together in Expert Advisory Committees (EACs), which form a collective body of expertise that publishes recommendations and opinions in line with scientific knowledge (4).

EAC members have a duty to act independently of the public authorities they serve, as well as the general public. However, recent controversies involving EAC members in conflict of interest who have influenced public decisions to their advantage — e.g., H1N1 (5), Tamiflu (6), Ebola (7) — have shaken certain public institutions and undermined public confidence in decision-makers. When there is a lack of transparency within EACs, this contributes to a crisis of legitimacy such as that experienced in recent years by democratic institutions in Canada (8). Indeed, when a growing number of people do not adhere to the dominant values on which the authorities and their decisions are based (for example, if they

do not act with transparency and integrity), we witness this type of "crisis of legitimacy", i.e. a breakdown in the social balance (9).

Within EACs, the crisis of legitimacy is exacerbated by the professional context in which expert members operate, since this creates situations from which conflicts of interest may emerge. Expert members are mandated by public authorities; they have a role to play in protecting the public and they must act independently. At the same time, as researchers, they are faced with increasingly limited public funding and the government's desire to encourage collaboration between academia and the private sector (10-12). This reality pushes researchers closer to private companies, creating a relationship of dependence. In fact, it is the companies that fund (wholly or in part) their projects and enable the experts to produce scientific knowledge in their field of expertise (12,13).

Like other EACs set up by public institutions, Expert Advisory Committees on Immunisation (EACI) are publicly funded and vested with powers and responsibilities by democratically elected governments. They play a crucial social role in protecting the health and well-being of communities and have the power to influence public policy (3,14). It is therefore essential that their decisions are transparent and that they are aimed at the well-being of the population, without being influenced by secondary interests such as financial gain or the desire to secure funding for research projects. Codes of ethics and mechanisms for disclosing interests and managing conflicts of interest are essential if EACIs are to legitimise their activities by imposing scientific and ethical principles on their members to guide their practice. Not only is it essential that these codes and mechanisms exist, but it is also desirable that they be disclosed to the public in order to enhance the accountability of expert members (and of the EACI as an organisation with a public role) to the public (15,16). The following case study presents a portrait of the dilemmas that members of an EACI may experience and seeks to stimulate reflection on the necessary elements to consider in order to ensure sound disclosure and transparent management of their interests.

Case study

The following fictional case presents the integration of a new member into a provincial EACI during a meeting to establish the recommendations to be issued to the Ministère de la Santé et des Services sociaux (MSSS) concerning the revaccination of adolescents against certain vaccine-preventable diseases (VPDs). As required by the protocol for integrating a new member into the EACI, the experts disclosed their respective conflicts of interest to the team, leading to some very interesting discussions and stimulating collective reflection.

Mr. Beaulieu is a professor in the Department of Social and Preventive Medicine at a Quebec university and a new member of the EACI. He is delighted with this new position, which allows him to contribute to the protection of public health by acting as an expert advisor to the MSSS.

He recently received an invitation to speak at an international scientific conference on the epidemiology of VPDs but had to decline the offer as he did not have the financial means to pay the travel costs. A few days later, he received an email from a BioMelior[1] representative. The representative offered to pay for his travel and conference registration. Enthused, he was surprised by the offer, as his research was not directly related to the company's products. Although this invitation is an excellent opportunity to promote his most recent work internationally, he is concerned about the invitation from a pharmaceutical company. He

[1] BioMelior is a fictional pharmaceutical company.

wonders whether he should disclose this information to his colleagues at his first meeting with the EACI. He was worried that it would be perceived badly, and he didn't want to put his new position at risk.

At the meeting to establish the recommendations and strategies to be proposed to the MSSS on the revaccination of adolescents, the EACI Chair, Mr. Zhui, introduced Mr. Beaulieu and reminded him that, under the Directive on the Prevention and Management of Conflicts of Interest (17), the integration of a new member requires each member to summarise his or her conflict-of-interest situations.

Ms. Mousseau, an active member of the committee, doctor and researcher, stated that she had investments in the capital of a company producing vaccines that the EACI evaluates when the MSSS mandates it to issue recommendations on the types of vaccines to recommend. This announcement surprised and shocked the other members. Faced with the obvious unease of her colleagues, she pointed out that these investments were minimal and that they had never affected her interventions at meetings.

Mr. Vinsky also spoke, indicating that he receives several hundred thousand dollars a year in subsidies from companies to carry out his epidemiology projects. He says that he really has no choice. If he relied solely on public funding, he would not be able to carry out a sufficient number of research activities. Several of the experts around the table agreed that this was also the case for them. Most of them receive funding directly or through their institutions from industry.

Ms. Mousseau confronts Mr. Vinsky with a little bitterness. She points out that, after all, his situation is just as likely to put him in a difficult position as hers. In fact, it is these funds that enable him to carry on his activities and, by the same token, build his reputation. Irritated by this comment, Mr. Vinsky informed the group that the grants he receives are mostly non-restrictive and that he therefore does not have to censor himself or alter the analysis of his data to please the industry. He went on to assert that there was a direct correlation between the profits of the company in which Ms. Mousseau invested and the income she derived from it.

Sensing that tempers were flaring, Mr. Zhui reassured his colleagues that if they were present at this table, it was because the institution they served had confidence in their judgement and the quality of their interventions. He added that if this were not the case, he had a number of measures at his disposal to limit their participation in the EACI or even exclude them.

Listening attentively to the discussions, Mr. Beaulieu was relieved: not only were several colleagues also in delicate situations, but they seemed equally perplexed as to how to respond. In the end, he shared his concerns with the EACI members about the invitation he received for the international congress. He told them about the situation and his unease about the e-mail from the BioMelior representative and asked for their advice. They all reassured him that he was not the first member of the committee to find himself in such a situation. Mr. Zhui added that it was not uncommon for invitations to conferences to cover all travel and registration costs. Mr. Vinsky points out that what is important is that the invitation is not unreasonable and that it only covers his expenses, without paying him or his family.

Once the tour de table and the meeting were over, Mr Zhui returned to his office, pensive. As a researcher himself, he knows how complex it can be to manage conflicts of interest, and the members' interventions lead him to wonder whether EACI's current disclosure and

conflict of interest management documents really do a good job of moderating the potential influence of members' interests on the committee's activities. Perhaps, as Chairman, he should initiate a collective reflection within the EACI to better develop the documents dedicated to the disclosure and management of conflicts of interest so that they respond more adequately to the situations faced by expert members? Would this be sufficient and appropriate assistance to equip EACI experts? He will share this idea at the next meeting.

Questions

The situation described above paints a picture of dilemmas experienced by members of an EACI that merit further reflection. Throughout the exercise, please identify the ethical principles on which your reflections are based.

On an individual level

- Should Mr. Vinsky accept restrictive grants? What are the implications of such grants for the researcher's autonomy?
- What are BioMelior's motives behind the offer made to Mr. Beaulieu? What risks does he run by accepting their offer?
- Since the Chairman of the EACI may himself be in a conflict-of-interest situation, is he in a legitimate position to assess and manage the conflicts of interest declared by his colleagues?
- Do the situations in which Mr. Vinsky and Ms. Mousseau find themselves involve the same level of risk? How could this be assessed? Is one of them more likely to influence the autonomy and judgement of these two members?

From an organisational point of view

- What should each expert member disclose when he or she joins the EACI? To whom? How?
- After joining, how proactive should each expert member be in disclosing his or her potentially conflicting interests?
- Is the disclosure of interests sufficient to ensure that a conflict of interest is properly managed?
- Should the declarations of interest of EACI members be made public? Are some conflicts of interest more problematic than others?

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Integrity in research: resisting conflicts of interest, fraud, bribes and other forms of corruption in research

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Original version: Abtroun SN, Williams-Jones B. L'intégrité en recherche : résister aux conflits d'intérêts et autres formes de corruption de la recherche. In: Piron F, Arsenault E, editors. *Guide décolonisé et pluriversel de formation à la recherche en sciences sociales et humaines*. ESBC; 2019.

Abstract

In order to promote responsible conduct and best practice in research, it is important to make researchers and students aware of conflicts of interest. The aim of this chapter is to identify conflicts of interest and learn how to assess the situations in which they may arise, so that they can be properly managed, and the scientific integrity of researchers maintained.

Introduction

Researchers in developing countries face many challenges on a daily basis. The constant race for performance and funding makes researchers vulnerable to conflicts of interest (COI) and risks of misconduct, sometimes exacerbated by the absence of guidelines or standards of responsible research conduct adapted to their particular context (1,2).

There are many definitions, but in general, a COI is a situation in which a person has an interest that is significant enough to influence their ability to exercise judgement in their professional practice or may be suspected of not acting impartially (3). Thus, it "may arise when activities or situations place an individual or organisation in the presence of interests (personal, institutional or other) that conflict with the interests inherent in the duties and responsibilities associated with their status or function."[1]

A COI is a situation that can undermine the very integrity of the research being conducted, compromising the results obtained, with negative repercussions for the researcher, his or her team and institution. COI can undermine the confidence of the scientific community and the public. They therefore raise ethical issues of responsibility and justice. However, problems arise mainly because of a lack of identification and appropriate management. This chapter will therefore help to raise awareness of COI among researchers and students and to teach them how to identify and assess these situations so that COI can be properly managed, thereby promoting responsible conduct in research and best practice.

The term COI itself is often associated with a pejorative view, meaning misconduct or even fraud (4,5). This erroneous perception leads some people to think that only people with malicious intent and who commit fraud are confronted with COI. As a result of this confusion, many researchers are either unaware of existing situations of COI or do not disclose them so as not to be suspected of a lack of integrity. However, COI do not mean fraud or misconduct... While some COI are particularly problematic and should therefore be avoided, others are ubiquitous in the research field (6): they need to be identified and managed correctly, and honesty and transparency must therefore be the order of the day so as not to damage the integrity of the researcher and the research field.

[1] Université de Montréal. Declaration of interest.

Types of conflicts of interest

The most visible CIs — those that raise discussions in the media and are the subject of political debate — are those linked to a financial interest, i.e. the methods of funding researchers and experts and their links with the private sector. When researchers receive gifts, paid travel expenses or research grants from private companies, they may put their personal interests ahead of the interests of the research (e.g. advancing knowledge rigorously, objectively and transparently). These situations, which give rise to real COI, are in contradiction with the professional duties and responsibilities of researchers (5,7). But non-financial COI can be just as problematic, and often harder to identify. For example, COI may be due to:

1. Power relations between student and teacher-researcher: it is difficult for the student to oppose the wishes of the researcher, who has his or her own interests that may diverge from those of the student, who is also the teacher or supervisor in charge of the student's assessments and academic progress (e.g. research subject, authorisation of scientific publications);

2. Relationships between researchers at the same institution: one researcher may have a personal interest to favour over another (e.g. prestige, competitiveness for limited resources), which creates bias in the evaluation or dissemination of this research (e.g. order of authors on a scientific publication, participation in conferences, peer review of grants or scientific articles);

3. Relations between the institution and teacher-researchers in the allocation of workloads (e.g. teaching, administration): often, some junior researchers have less scientific freedom and do more work than senior researchers (e.g. choice of research project or team, participation in committees) (5).

Management resources

It's important to identify and assess COI, and you need to start by asking the right questions to consider the risks involved:

- Which players are involved in the COI?
- What responsibilities are in conflict?
- What interests are in conflict?
- Are the interests significant for the players involved?
- Are reputations (individual, institutional) at risk?
- How is the COI perceived by people outside the establishment?
- What are the risks and damage caused by the COI?
- Which players could be affected by these risks and damage?

With these questions in mind, it is then possible to think about COI management.

Case study

Tamara is a PhD student in a biology laboratory in West Africa. She is currently working on a research project in the team of an internationally renowned African university researcher: Prof. Reference. The project involves developing a non-polluting fertiliser that can improve agricultural productivity in poor soils. The project is mainly funded by a multinational company (Firm M), which has great hopes for the development of this low-cost product, which could be marketed in all developing countries. The principal researcher, Professor Reference, informs Tamara that if the results of the research project are in line with those

hoped for, i.e. an effective, non-polluting fertiliser, they will receive an end-of-project bonus. Firm M will also fund two other projects for which Professor Reference will recruit Tamara as a full-time employee, and she will hold the position of project manager. However, when the data was analysed, Tamara discovered that the product was effective as a fertiliser as expected, but that it was a pollutant under certain specific conditions, accounting for 10% of the soil results tested, which was higher than expected.

Questions

1. What are the identifiable COI in this case? What are they?
2. What risks or research misconduct might Tamara give in to?
3. How can Tamara manage these situations and promote ethically responsible behaviour in research? What are her responsibilities to Professor Reference or to Firm M? And what responsibility does Professor Reference have to her student, to manage the situation properly?

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Articles

Explain the potential conflicts of interest to which health care workers are exposed when participating in emergency research activities

Marie-Josée Potvin, Bryn Williams-Jones

Original version: Potvin M-J, Williams-Jones B. Learning objective 7.3: Explain the potential conflicts of interest to which health care workers are exposed when participating in emergency research activities. Ethics in Epidemics, Emergencies and Disasters: Research, Surveillance and Patient Care, Training Manual, 1st Edition, World Health Organization; 2015. p. 216-225.

Session timeline (90 min)

0-15 min (15 min)	16-25 min (10 min)	26-55 min (30 min)	56-85 min (30 min)	86-90 min (5 min)
Introduction	Presentation of problem-solving tools	Case study and discussion, phase 1	Case study and discussion, phases 2 and 3	Summary and conclusion

Instruction strategy

For facilitators: This session is highly interactive; it requires that you spend time familiarizing yourself with the content and format of the session.

1. The facilitator starts the session by presenting definitions and concepts (slides 1-4).
2. The facilitator presents the problem-solving tools (slides 5-7), highlighting the main approaches to identifying, evaluating and managing conflicts of interest.
3. The facilitator summarizes the model for ethical management of conflicts of interest.
4. The facilitator presents the first part of the case study (slide 8).

For facilitators: Provide a general overview of the case and discuss its key contextual features.

5. The facilitator moderates phase 1 of the analysis, using the "facilitators' discussion guide", below.
6. The facilitator progressively presents parts 2a-2c of the case study (slide 8) and moderates phases 2 and 3 of the analysis, using the "facilitators' discussion guide".

For facilitators: Present progressively the contextual elements of the case. Introduce various scenarios to show that it is essential to understand the social, political and cultural context. Identify contextual factors and ask questions that will help students to identify potential conflicts of interest.

When progressing to phase 3, help participants to reflect on the lessons that can be learnt from ethical analysis of the case about how things could have been managed differently to avoid the problems identified.

7. The facilitator concludes the session and opens the floor for discussion.

A. Background

Public health research involves a wide variety of stakeholders (e.g., researchers, populations, politicians, policy-makers) with different, often conflicting and sometimes irreconcilable

interests at multiple levels (e.g. intervention, research, policies). This context provides fertile ground for conflicts of interest.

In public health emergencies with a dramatic human impact and significant uncertainty, it is impracticable and unreasonable to expect researchers or health care workers to identify, analyse and manage conflicts of interest when they have other pressing responsibilities (1). In addition, when powerful stakeholders with vested commercial or political interests are involved, effective policies to prevent conflicts of interest may be difficult to both elaborate and implement (2,3). As there is no clear definition of "conflict of interest" explicitly related to research in emergencies and as pressure to elaborate and apply conflict of interest policies is likely to be exerted by academia and civil society, researchers working in the context of emergencies with public health consequences must familiarize themselves with the notion. Both education and strong public health research policies should be developed at all levels that both define acceptable and unacceptable behaviour and provide clear procedures and guidance. These policies should be supported by sufficient political leverage to ensure their application in research during emergencies.

B. Topics

Defining conflicts of interests

The term "conflict of interest" is often viewed as or equated with fraud or ethical misconduct (4). For many people, the term is necessarily pejorative (5). In the world of health research and professional practice, this perception is most likely due to highly publicized scandals involving poor management of financial conflicts of interest, such as in the case of industry involvement in studies of meningitis in Nigeria (1). The resulting media coverage arguably helped to undermine public confidence in the integrity of researchers, academic institutions and health professionals (6-8).

Unfortunately, this pejorative view helps to make the concept of conflict of interest largely unusable: if, in people's minds, it is equated with fraud or misconduct, it follows that only "bad people" have conflicts of interest. Therefore, goes the thinking, a well-intentioned person can have no conflict of interest. The truth is, however, that conflicts of interest are frequent in research and professional practice, and there is nothing inherently blameworthy about having such a conflict. Institutional arrangements in fact sometimes make them probable, if not inevitable (9). If actual or apparent conflicts of interest are inappropriately managed or, worse yet, not addressed or covered up, they can seriously damage the trust of colleagues, patients and the public in professionals and their institutions. It is essential, then, to use effective, transparent strategies to identify, evaluate and manage those conflicts of interest that cannot be avoided, such as disclosure to stakeholders, excluding individuals from certain decision-making and the involvement of neutral third parties.

The definitions tend to concur that a conflict of interest is necessarily associated with a process of judgement or decision-making and that they most often arise in situations in which an individual or group has to make an objective or impartial decision. A conflict of interest may thus be internal to an individual researcher, health care worker or community leader, for example, or external and thus structurally embedded or part of collective decision-making.

If the definitions of conflict of interest are relatively simple to understand, at least conceptually, they may be difficult to apply in distinguishing what is and is not a conflict of interest. They are, for example, often confounded with conflicts of role and loyalty. Although these can indeed be conflicts of interest, they are not necessarily. In the case of a physician-

researcher employed by a pharmaceutical company, the two affiliations may put the individual at risk for uncomfortable inner conflicts, especially in the context of research during an emergency. Which role should take precedence e.g. in terms of priority or time commitment? That of the physician with a duty to respond to the medical health needs of a population or that of the researcher whose responsibility should be to focus on the good conduct of the study? This conflict is an example of a conflict of loyalties and roles, which creates situations as equally problematic as a conflict of interest but that are only related to and not synonymous with it. This situation could, however, create a challenging conflict of interest if the interests or responsibilities of one professional role (e.g., a researcher focused on advancing knowledge) create bias that undermines the responsibilities of the other role (e.g. a clinician focused on advancing a patient's best interests).

In order to become more expert in recognizing and managing conflicts of interest in public health research or surveillance, researchers, health care workers and others must make an active commitment to individual reflexivity and preparation and individual and collective analysis.

One strategy for recognizing a conflict of interest is to determine the conditions or characteristics of the situation. A variety of actors or stakeholders are often implicated, and it is important to recognize who those actors are and their interests (e.g. personal and not financial, financial, institutional), in order to identify the conflicts that could arise, the risks that they create and for whom. Only then can it be possible to evaluate the severity of the risks posed by the conflict and determine the most appropriate management strategy.

Types of conflicts of interests

Financial

In the context of public health research, obvious financial conflicts of interest can occur in the relationship between clinical scientists and the private sector (10). Researchers have a conflict of interest if they prioritize personal interests (e.g. money, promotion) over their professional duties, such as protecting the welfare of participants or ensuring the integrity of the scientific process. Similarly, community leaders working in collaboration with public health researchers may have financial interests that conflict with their responsibilities to either their community or the researchers.

Non-financial

Conflicts of interest are not always financial, nor are they always those of people who, at first glance, may appear to have the most power or influence. Research-related conflicts of interest may be associated with local politics and be more difficult to detect. They may also arise within the community in which research is being conducted. Some community leaders might want to benefit from a research project, for example, to enhance their reputation in the community and therefore try to please the investigators rather than provide support for the research endeavour (11).

It is important to pay attention to the risks associated with conflicts of interest for both vulnerable people and for the more powerful actors who may be involved. Some groups, such as patients and vulnerable populations, might lack the capacity to judge fully the interests of those with whom they are interacting or to resist those interests. For example, some potential research participants might have no other means of accessing necessary health care than to "consent" to a project, in which the principal investigator might have

three different roles and interests: researcher, health care provider and shareholder in the company for which the drug is being tested (11).

Even people in more powerful positions, such as researchers and health care workers, may risk being involved in, or associated with, a conflict of interest. The risks are most commonly loss of trust in both the individual and the profession but also in research findings and the research establishment. Such loss of trust can endanger established working relationships (inside and outside the research team) as well as international collaboration, thus negatively affecting the safety of the patient or participant and, ultimately, public health.

Contexts in which conflicts of interests occur

Context is central to both the identification and the management of conflicts of interest. The detailed context is, however, rarely evident at first glance and even less so in an emergency. To complicate matters further, although some insight can be gained from anticipating the type of context, factors and situations often evolve and can change dramatically and rapidly. Therefore, for effective management of a conflict of interest, it is important to be prepared for multiple scenarios. Thinking proactively and being well prepared can help refine understanding and the capacity to quickly recognize and address conflicts of interest, leaving resources (time, energy) to process new insights and deal with unresolved conflicts that are more likely to have negative consequences.

C. Case study

Source: Cash et al. (11)

Part 1

The staff-benefits group of a West African mining company asks a research team based at a European university to help determine the economic impact of the AIDS epidemic on their workforce. The group wants to convince senior management that the cost is much higher than expected. They suspect that absenteeism due to AIDS, rapid turnover of highly trained and semi-skilled staff (leading to re-training costs), treatment costs for the illness, one-time benefits and funeral costs to the families of affected workers have been underestimated.

The research centre puts together a team consisting of a physician, an economist, a public health specialist and a research associate and travels to the country for 3 weeks of intensive fieldwork and investigation. At their request, the team is given access to the records of all employees who had to leave the company because of AIDS or AIDS-related illness. Any data that could identify individual employees are removed from the records. No data on the prevalence of infection exist in the company, but sample surveys have been done in other parts of the country to examine the rates of HIV infection in similar age groups.

Part 2a

The staff-benefits group hopes that, if they demonstrate the costs of the epidemic, the company will provide more preventive programmes, such as distribution of pamphlets, lectures at the workplace and recreational activities for single men who live at the company hostels, some of whom frequent a nearby area with a high concentration of commercial sex workers. Preventive and educational services could also be provided to the families of married workers. Other interventions might include establishment of clinics to treat sexually transmitted infections more aggressively or long-term provision of family housing units. The staff-benefits group believes that a report from a well-respected university research group will be an effective way to influence company policy and promote preventive programmes.

Part 2b

The research team will be fully funded by the company, including overhead payments commensurate with university guidelines. The company has stated that it will not restrict the researchers' ability to publish the study findings, although it will require that the company and all its employees remain anonymous in any reports or publications.

As data collection nears completion and the research team prepares to return home to analyse the data and prepare the report, a senior member of a trade union requests a private meeting. He expresses concern that the company will not use the results of the study to improve public health programmes but will instead conclude that anyone who is HIV-positive will be too costly to retain and that therefore even HIV-positive individuals who are still healthy will be released on some pretext. Although the company is barred from testing new employees, it can require that employees obtain private health insurance, which often requires an HIV test. Finally, he states that the company will probably cut back its workforce (and therefore decrease its liability) by downsizing and outsourcing.

The team members request a meeting with the sponsors of the research and, without disclosing their source, express their concern that the report could be used for purposes that are contrary to their intentions. The company insists that any rumours they may have heard about misuse of the report are untrue. However, the research associate is not satisfied with the company's explanation and asserts that, unless the company provides an assurance in writing, she will immediately withdraw from the project. The company says that it cannot sign such a statement, as doing so would reflect badly on the integrity of the organization.

The research team analyses the data and presents the following conclusions to the management of the company before publication:

- The prevalence of HIV infection in the general population will probably mean an employee turnover rate of at least 10% per year for the company.
- The health care costs for the company will increase significantly over the next 5 years and could constitute 15% of its total operational costs. By law, if an employee's illness is diagnosed while he or she is working for a company, all the health care costs related to that illness must be paid by the company, whether or not the illness is work-related.
- To reduce costs, the company should begin a home-treatment program for employees with AIDS.
- Prevention programmes would almost certainly reduce the incidence of HIV infection among employees, although the cost-effectiveness of these programmes is not known.

Part 2c

Managers at the company are alarmed by the report and by the projected costs of caring for HIV-positive employees. The chief executive officer says that, if the company is forced to take on the health care costs of all employees who become HIV-positive during their employment, it will be unable to compete in the international market and will be forced to declare bankruptcy or relocate to a lower-cost country that does not make the same demands. In either case, everyone at the company will lose their job, leaving many households without any income.

He asks that the research team take this issue into account in writing their conclusions. In fact, he asks the team to recommend that employer-subsidized health insurance plans be allowed to cap benefits for HIV infection at far less than the cost of the treatment needed. Employees with HIV infection would then either pay for their own treatment, forgo treatment

or rely on publicly provided services. Households and extended families would probably bear the brunt of the costs, as the health care facilities of government and nongovernmental organizations are already overwhelmed with HIV/AIDS patients. The chief executive officer argues that transferring the costs to the government, households and other companies is a rational response for a profit-maximizing business. Given the international reputation of the research team, he expresses confidence that a report that recommends a cap on benefit will persuade government regulators to change their policy.

Facilitators' discussion guide

Part 1

Ask participants to identify the main actors in the situation and the potential conflicts of interest that may emerge.

For facilitators: The actors may include people not explicitly identified in the case, such as politicians and company shareholders. Anticipating the existence of these actors may minimize potential conflicts of interest. Use the table below to guide the discussion on the main actors involved and their interests. Ask participants to list the obvious primary (real or potential) interests of each actor.

Encourage students to start thinking proactively by identifying possible scenarios for the case of conflict of interest with which they might be confronted. This will make them more aware from the beginning of the possible interests at stake and thus help them to identify and embody their own interests in their roles and duties as researchers or health care workers. Use the table below to guide the discussion about the actors' interests.

Identify the main actors involved	• Each actor's real or potential (future) interests
Research team at a European University	• Produce valid research data in public health to participate in knowledge development • Population health; public good or interest • University, research group and recognition or prestige of researchers • University and research group financing
A staff-benefits group of a West African mining company	• Workers' benefits (health, financial) • Community well-being • Settle old battles with the employer
West African mining company	• Financial health of the business • Political interests • Response to shareholder pressure
Highly trained workers and semi-skilled staff	• Personal benefits (good job, financial, housing conditions)
Workers' unions	• Workers' interests • Union's interests
Community organization	• Community interests • Workers' interests
Nongovernmental organization	• Sustainability of operations, reputation, influence • Community, global interests
Shareholders	• Financial interests (profit)
Political actors (local, national, international)	• Economic development • Political interest (power, influence)

Ask participants to identify possible conflicts of interest and briefly discuss their associated risks, and use the table below to guide the discussion.

1. The mining company may have financial and/or political interests, and our results may be seen as a means to bring them to fruition.

• Potential conflict of interest for researchers: What if the results are not in line with the mining company's agenda (valid research and integrity versus funds for the research group (a contract)?
• Possible consequences:
  o High interpersonal tension
  o Impossibility of publishing valid research results that might help to improve workers' conditions and community well-being overall
• Risk: High, because it is directly related to the researchers' primary interest.

2. We may suspect that unions will eventually be involved and bring in old, enduring conflicts between the workers and the company (e.g. salary, contracts).

• Potential conflict of interest: possible pressure from the union if the results go against the interests of the workers.
• Possible consequences:
  o Overstating the findings of the research in order to help the workers, considered as victims, to gain better working conditions
  o Alternatively, overly prudent analysis
  o Strong political tension in the mining company
• Risk: High, because it is directly related to the researchers' primary interest, it may be seen as an intrusion into the political matters of another country.

3. We may wonder whether local political actors also have political or financial interests in the survival of the mining company; this could be an added pressure that might interfere with the research process.

• Potential conflicts of interest:
  o Pressure possibly added to those of the company in order to orient the process to their advantage
  o Subtle pressure (e.g. invitations for meals, gifts or other incentives)
• Possible consequence: Impasse in which the research group might be suspected of corrupting the results (whatever the analysis) and is mistrusted by the workers and the general population.
• Risk: High, because it is directly related to the researchers' primary interests, it may undermine population trust and jeopardize other, future research projects in the population.

4. We may wonder whether local politicians also have political or financial interests and may question our own interest in carrying out the project, beyond a simple "search for knowledge".
• Potential conflict of interest: The pressure to make "positive" findings that can be published, to maintain good research environments and to succeed with academic promotion. • Possible consequence: Situation that makes you more tolerant to questionable practices because you do not want the project to be compromised; it will be an excellent addition to your curriculum vitae, thus enhancing your opportunities. • Risk: High and low, because it is directly related to the researchers' primary interest, but you have control over it.

Part 2

After each addition of contextual information (parts 2a – 2c), ask participants the following questions:

- How do the new contextual elements affect your analysis of part 1?
- Are there emerging conflicts of interest (actual and/or potential)?
- Can you briefly discuss the risks associated with these emerging conflicts of interest?

In conclusion, ask participants what they consider important in managing conflicts of interest on the basis of the discussion so far and the specificity of research in an emergency context. Use the following points to enrich the concluding discussion.

Messages specific to the case study

- In this situation, by taking a proactive approach, we could have reduced the chance of having to manage a delicate conflict of interest that was perhaps inevitable but probably manageable.
- We could have asked better questions (e.g., about interests, the political and institutional context) and provided solutions on which the whole group could have agreed from the start (e.g. personal and professional limits, priority given to private interest or research and the public interest).

General messages

- Be better prepared, less stressed and thus more efficient in decision-making.
- Better understand the scope of responsibility and basic ethical rules for all actors involved.
- Involve, when needed, experts (e.g., in policy, political science, anthropology) to better understand the whole context of the research project.
- Undertake *a priori* and *a posteriori* discussions with the research ethics committee on conflicts of interest and communicate your experience to inform other groups.
- Encourage dialogue about conflicts of interest during the research project.
- Inform and educate as many people involved in the project as you can. Consider that everyone is part of the problem and of the solution.
- Communicate your experience to the team, researchers and policymakers, when possible (e.g., in research publications), and enrich this educational material by adding examples of your own and other situations of conflict of interest.

D. Summary

To become more expert at recognizing and managing conflicts of interest in public health research or surveillance contexts, researchers, health care workers and other actors will have to increase their individual reflexivity, individual and collective preparation and continuing analysis. The goal of this module, to improve the identification and management of conflicts of interest in practice, might seem idealistic, as the realities faced by researchers and health care workers already pose an overwhelming variety of challenges. Nonetheless, this module has an attainable goal, to propose a means and an opportunity to discuss a delicate matter — one that is often taboo — that can have a significant negative impact not only on research integrity but also on individuals (e.g. injustice, stress) and whole communities (e.g. resource distribution, policy-making). The context of emergency situations is highly unpredictable, making it all the more important to learn from experience. This module presents a practical, pragmatic approach for collecting, organizing and communicating information about experiences with conflicts of interest in order to prevent or manage those that can be

predicted in advance and to deal with unpredicted or inevitable conflicts that arise in the context of public health practice.

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Coalition Priorité Cancer and the pharmaceutical industry in Quebec: Conflicts of interest influence in the reimbursement of expensive cancer drugs?

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Original version: Hughes D, Williams-Jones B. Coalition Priorité Cancer and the pharmaceutical industry in Quebec: Conflicts of interest influence in the reimbursement of expensive cancer drugs? Healthcare Policy. 2013;9(1):52-64.

Acknowledgements

The authors would like to thank Sharon Batt for helpful remarks on drafts of the manuscript. Many of the ideas here have benefited from ongoing critique and discussion with the Conflict-of-Interest Research Group at the Université de Montréal. Hughes was supported by scholarships from the Fonds de recherche du Québec — Société et culture (FRQ-SC). This research was supported by grants to Williams-Jones, from the FRQ-SC and the Ethics Office of Canadian Institutes of Health Research (CIHR).

Abstract

In the context of scarce public resources, patient interest groups have increasingly turned to private organizations for financing, including the pharmaceutical industry. This practice puts advocacy groups in a situation of potential conflicts between the interests of patients and those of the drug companies. The interests of patients and industry can converge on issues related to the approval and reimbursement of medications. But even on this issue, interests do not always align perfectly. Using the Quebec example of Coalition Priorité Cancer (CPC) as a case study, we examine the ethical issues raised by such financial relationships in the context of drug reimbursement decision-making. We collected, compiled and analyzed publicly available information on the CPC's organization and activities; this approach allowed us to raise and discuss important questions regarding the possible influence exerted on patient groups by donors. We conclude with some recommendations.

In October 2011, the national institute for excellence in health and social Services of Quebec (INESSS) announced that for cost-effectiveness reasons, it could not recommend to the Ministry of Health the reimbursement of four cancer drugs that were under evaluation: Iressa, Tarceva and Alimta for lung cancer, and Afinitor for kidney cancer. This decision was immediately denounced by Coalition Priorité Cancer (CPC) — a Quebec-based patient advocacy group (1). The CPC critique was taken up in the Quebec National Assembly by the then official opposition, the Parti Québecois, further increasing pressure on the Liberal Minister of Health at the time, Dr. Yves Bolduc. The Minister intervened with INESSS and, in November 2011, announced the reimbursement of three of the four drugs that had initially been rejected (Iressa, Tarceva and Alimta) (2). Following this shift, an article published in the French-language newspaper, Le Devoir, raised questions about the possible influence that the pharmaceutical industry had on the CPC (3) and, by extension, on government decision-making. Specifically, the article pointed out that the manufacturers of the drugs in question — AstraZeneca, Eli Lilly, Hoffman-LaRoche and Novartis — had each provided significant financial support to the CPC, bringing into question the interest group's independence and the potential for indirect influence of the pharmaceutical industry on

government decisions. This story was then picked up by various media, to which the CPC responded by reaffirming its independence (4).

Pharmaceutical industry funding of patient or disease interest groups raises important ethical issues related to conflicts of interest (COIs) and public trust. Of particular concern is the "subversion" or "co-opting" of patient interest groups to advance industry agendas. Using the Quebec example of CPC as a case study, we will examine the ethical challenges — and in particular, the financial COIs — faced by patient interest groups, in order to reflect on the responsibilities of both these groups and industry with regard to the very problematic COIs that arise when the latter contribute to financing the activities of the former.

Background

Patient interest or advocacy groups commonly provide their members (i.e., patients and their families) with accessible information about their condition (e.g., aetiology, possible treatments) and support to live with the condition. Some of these groups also try to encourage research on their specific condition by engaging in public fundraising campaigns and calling upon policy makers to create more favourable conditions for the conduct of research and the development of treatments. These groups can also represent their patient-members in the media and before government, appearing before or even participating as members of regulatory agencies and health policy or public advisory committees (e.g., patient interest groups are represented on the Australian Pharmaceutical Benefits Advisory Committee and on committees of the UK evaluation agency, the National Institute for Health and Care Excellence [NICE]) (5,6).

Patient interest groups are largely volunteer run and often function with very limited operating funds, much of which come from private donations but also from government grants. In the last few decades, however, governments in many developing countries have significantly reduced funding to citizen groups of all sorts. In Canada, since the 1990s, a context of fiscal restraint and a changing public role of citizen groups has led to a substantial reduction in the funding of interest groups by the federal government (7). As such, patient groups have increasingly chosen to turn to private organizations, including the pharmaceutical industry, to find funding for their various activities. A study by Ball and colleagues (8) of patient interest groups in the United States, the United Kingdom, Australia, Canada and South Africa found that of 69 groups studied, 45% declared industry funding on their group websites. Similarly, Hemminki and colleagues (9) found that 71% of groups in Finland were funded by drug manufacturers, while O'Donovan (10) noted industry support in at least 47% of groups in Ireland.

From the perspective of the pharmaceutical industry, an association with patient interest groups has many advantages. Such collaborations enable interest groups, and thus patients, both to access and to share information regarding manufacturer products that are directly related to their conditions. In addition, because interest groups put a human face on disease, they add credibility to causes that the industry advocates (6,9). But relations between patient interest groups and the pharmaceutical industry are extremely varied and can be characterized by refusing funding on the one hand, and cooperation or even co-optation on the other.

1. Refusing industry funding: Some groups refuse any funding from industry, motivated by political reasons or the desire to maintain their independence and public credibility. For example, Breast Cancer Action of San Francisco explicitly refuses industry funding to safeguard its credibility and political legitimacy (10,11). Breast Cancer Action

Montreal and the Society for Diabetic Rights are examples of this type of group in Canada. Some health consumer groups, such as Women and Health Protection, PharmaWatch and the Canadian Health Coalition, also operate completely independently of industry funding.[1]

2. Cooperation: Groups that agree to accept some industry funding may be more or less cautious in their relations. They may require different degrees of disclosure in their annual reports or on their websites (simply the names of donors, full disclosure of amounts received, program funded or percentage of total budget). In cases of project funding and activity sponsorship, Canadian Cancer Action Network's policy stipulates that "the sponsor will be acknowledged in a way that is agreed in negotiations with the company." Unlike most groups, Epilepsy Action Australia specifies the amounts of donations from drug companies in its annual report (8). Some groups may also require "no strings attached" agreements for any funding in order to maintain their independence. For example, Fibromyalgia and Chronic Fatigue Syndrome Canada's policy requires a written agreement "recognizing the autonomy and independence of FM-CFS Canada and its activities separate from any influence of the supporting company." It also requires that all educational grants be unrestricted (12). However, the Canadian Cancer Action Network's policy, while maintaining its groups' editorial control over all material, allows companies that fund specific projects to have representation on its steering committee (13). Other groups may be much less concerned with the problems that can result from such partnerships and not have formal guidelines or procedures.

3. Co-optation: There are some cases where organizations have been completely co-opted by industry (e.g., Society for Women's Health Research in the United States (14)) or even created from scratch by the industry while still giving the appearance of being independent grassroots organizations (10,15). Yet, if these groups become seen as representing the interests of industry, they then run the risk of losing their public credibility and utility for industry (15-17).

The interests of patients and industry can converge on issues related to the approval and reimbursement of medications (9,18). Patients and interest groups legitimately desire access to better and more effective medicines, while the industry is interested in expanding its market share or getting a new medication reimbursed by health insurers. When such interests align, it may be very advantageous for manufacturers to finance the activities of patient interest groups.

In lobbying governments and intervening in the media, patient groups can be very effective at advancing certain agendas. These groups can influence the decisions of evaluation agencies (and have done so in the past) in favour of certain medications, or even contribute to overturning decisions regarding inclusion in drug insurance plans (19). For example, the UK Alzheimer's Society's campaign against a NICE decision contributed to widened access to Aricept, Exelon, Reminyl and Ebixa (20). In addition, Carpenter (21) has shown that the time required for the US Food and Drug Administration (FDA) to review and approve a drug was shorter when the medical condition in question was represented by advocacy groups that were well organized and funded. However, this type of relationship can lead to important pitfalls. For example, a study among European patient and consumer

[1] Because the mission of most consumer groups is to protect consumers from corporate abuse (e.g., misleading advertising), they are much less likely than other advocacy groups (e.g., patient groups) to accept funding from drug companies.

organizations has revealed an association between receiving drug company funding and supporting an expanded role for these companies as information providers (22). Potential problems are even explicitly recognized by Canada's Research-Based Pharmaceutical Companies, the association that represents the pharmaceutical industry: "Given the range of issues in common, it is natural that the pharmaceutical industry and stakeholder groups should work together. However, the industry also recognizes that there exists the potential for conflict of interest, either real or perceived, in the relationship" (23).

In this paper, we focus on the case of Coalition Priorité Cancer (CPC), a Quebec-based patient interest group that is very active on issues of oncological drug reimbursement. While likely an outlier among the diverse patient interest groups in Quebec in terms of its industry funding (which is substantial), its influence with provincial decision-makers makes it an important actor to study, and a notable example of the challenges both for patient groups and for the pharmaceutical industry in managing potentially very problematic COIs.

Methods

For this study, we followed three general steps. First, we conducted a broad, non-systematic literature review on the relationship between patient groups and drug companies to identify key analytical elements and main problems related to such relationships. Second, we collected all the information publicly available on the history and activities of CPC (Appendix 1) from its creation in 2001 to the end of 2011, as well as a list of its members (Appendix 2). Information sources on the CPC included:

1. The CPC website;
2. Newspaper stories (*La Presse*¸ *Le Devoir*);
3. Comments in the Quebec National Assembly;
4. Publicly available documents related to forums, symposia and conferences organized by the CPC (event programs, presentations, etc.);
5. Two special sections ("cahiers spéciaux") published by the CPC in the newspaper Le Soleil (2009 and 2011); and
6. Studies, polls and petitions ordered by the CPC.

Most of the information was obtained directly from the CPC website, but also by searching Google and the Quebec National Assembly's website for the keywords "Coalition Priorité Cancer." To select newspaper articles, we searched the Eureka database for the keywords "Coalition Priorité Cancer" to identify relevant articles in the French-language press in Quebec. (French in-text citations are translated into English, and newspaper stories are referenced: D = *Le Devoir* and P = *La Presse*, followed by date of publication). Third, CPC's organization, activities and interventions were analyzed deductively, based on the elements identified in the literature review. The content of newspapers was not inductively and independently analyzed. It was used just as were other sources of information on CPC. All three appendices were compiled by the authors. The information on evaluation status of drugs in Appendix 3 was obtained from the INESSS evaluation reports available on that agency's website.

Results and Discussion

The main analytical elements and potential issues that were identified in the literature were:

1. the portion of a patient interest group's income that comes from industry;
2. the fact that manufacturers tend to support groups working in their particular therapeutic areas — this provides a clue to the interested nature of their donations;

3. the influence of donors on the orientation of groups through funding certain activities rather than others;
4. the tendency of patient interest groups that receive industry funding to defend the industry's position that the drug assessment and approval process is too long and too strict — a position that focuses on access and may downplay other criteria, such as safety and efficient use of resources;
5. neglect by patient groups of questions about drug pricing and drug price policies; and
6. conflict of interest management and disclosure practices.

In the following discussion, we develop each point and explore points in relation to the case of CPC and to interest groups in general.

The CPC brings together 40 organizations (e.g., interest groups, professional organizations, university research chairs), and was established in 2001 to "defend and give a voice to those affected by cancer (patients, survivors, their families and their relatives) and to strengthen the organization of the fight against cancer" (24). The group's main declared objectives are:

- to develop — in partnership with various actors in the fight against cancer, including civil society leaders and political decision-makers — a provincial plan to fight cancer;
- to promote the creation of an agency to better coordinate and strengthen the fight against cancer;
- to propose and support any measure that improves services to all people affected by cancer;
- to develop partnerships between community organizations, the healthcare system and government;
- to ensure a continuous surveillance of the fight against cancer; and
- to educate, raise awareness and mobilize the public (24).

The CPC's activities include the production of surveys, petitions, forums, conferences, press conferences and press releases (Appendix 1). It is funded by contributions from member organizations (Appendix 2) on an annual basis or for a specific activity, individual registrations in the various CPC activities, and financial assistance from the public and private sectors, including 13 drug manufacturers (Appendix 3).

The portion of a patient interest group's operating funds that comes from industry, as compared with individual donations or government support, is a key issue raised in the literature. In some cases, the percentage of operating funds from industry may be relatively limited, such as 6% to 7% for the Canadian Arthritis Society or 9% in the case of Cancerbackup (25). But industry funding may be more substantial in some cases, reaching 30% for the Diabetes Federation of Ireland (10). In their study of 39 Finnish organizations that reported receiving funding from industry, Hemminki and colleagues (9) noted that for four groups, this funding represented more than 20% of their annual budgets. In the case of the CPC, 60% to 65% of its budget came from the pharmaceutical industry in 2011 (3), a figure that is extremely high when compared to other cases cited in the literature. Although the relative portion of an operating budget is one indicator of the importance of the financial COI, the absolute value of funding is also meaningful, as even a small percentage of a very large budget may represent a considerable amount of money.

A study by Rothman and colleagues (17) suggests that manufacturers tend to support groups working in their particular therapeutic areas. This implies, not surprisingly, that the industry's support of patient interest groups is not purely altruistic, but interested. Of the 13 pharmaceutical companies financially supporting the CPC in 2011-2012, all have an interest

in oncology. Moreover, in 2011-2012, the 13 manufacturers all had products either rejected in evaluation or not yet evaluated (Appendix 3). All these companies had a clear interest in seeing the CPC support their cases before decision-makers and regulators, especially concerning the approval and reimbursement of their drugs.

In the absence of "no strings attached" agreements, donors may have some influence on the orientation of groups by funding some activities rather than others. It should be noted that most CPC activities known to be specifically funded by drug companies deal with the issue of reimbursement of cancer drugs (conferences in 2010 and 2011; "cahiers spéciaux" in 2009 and 2011). From 2009 onwards, the issue of drug reimbursement assumed greater prominence in the CPC's activities, and in 2011 it became predominant.

Evaluation agencies such as INESSS in Quebec have the responsibility to make recommendations regarding the approval and reimbursement of pharmaceutical drugs based on their safety, effectiveness and efficiency (cost-benefit), and the fairness and sustainability of the drug offer. Batt (26) noted that Canadian health interest groups receiving industry funding (e.g., Best Medicine Coalition) tend to defend the industry's position that the drug assessment and approval process is too long and too strict. Conversely, those groups receiving no funding from industry (consumer groups such as Women and Health Protection, PharmaWatch and the Canadian Health Coalition) tend to advocate for greater drug regulation and safety standards, both before and after marketing. While patient interest groups are heterogeneous in their constitution, membership, mission and functioning, such a dichotomy between those groups that receive and those that do not receive industry funding can lead one to hypothesize that significant financial interests could have an important impact on or even shape the behaviour of these groups. The CPC fits the pattern because it has taken the industry's position on numerous occasions: e.g., "The Coalition therefore urges Québec to review the functioning of the Conseil [du médicament] that it considers too slow and too severe" (D.2010.12.09).

However, accelerating and easing the evaluation process is often associated with less evidence and more risk to patients (27). In this respect, the position of the CPC on Avastin, for metastatic breast cancer, appears problematic. Avastin was approved for this indication by the FDA in 2008 and by Health Canada in 2009, but these approvals were conditional on obtaining additional data, as efficacy and safety had not been clearly established. In June 2011, with no study having yet demonstrated the effectiveness and safety of Avastin for breast cancer, a study committee of the FDA recommended revoking the approval of the drug for this indication (28); in November, the FDA and Health Canada followed this recommendation (29). Yet, in October, although the FDA had already recommended the withdrawal of Avastin, the CPC denounced INESSS's rejection of eight cancer drugs for metastatic breast cancer, including Avastin (CPC press release 2011.10.04) (30). In its interventions, the CPC never mentioned the questions raised by the FDA study committee surrounding Avastin's safety and effectiveness for treating breast cancer.

The CPC's opinion on the unreasonable severity of the drug evaluation process not only concerned the criterion of therapeutic value, but also the criterion of efficiency (cost-benefit ratio): "The process of approval of these drugs is very long and, in cases of refusal, financial arguments take too much space, also deplores Dr. Audet-Lapointe" (P.2010.12.09). From our analysis and based on the information we collected, the evaluation criterion of efficiency does not appear to be relevant for the CPC. In fact, it often asks: "What is the cost of life in Quebec?" (CPC press release, 2011.10.04; P.2011.10.05). The underlying idea seems to be that life has no price. However, drug reimbursement without regard to costs is not a

responsible and efficient use of resources and can threaten the sustainability of drug insurance plans (19). In addition, any inclusion of a new drug has an opportunity cost, that is to say, it necessarily implies the abandonment of or reduction in access to another service (31). It is thus important to consider whether the reimbursement of these expensive, low-efficiency drugs constitutes the best use of resources in the fight against cancer (32).

Besides putting pressure on agencies and policy makers to approve and pay for certain drugs, patient interest groups could also put pressure on industry and governments to lower drug prices. However, as noted by Batt (11), "drug pricing in itself has been a neglected area for direct lobbying by patient and health advocacy groups in Canada" (p.12). This choice of target is probably not unrelated to the fact that many interest groups receive industry funding. But it might also be due to the fact that these groups have been less able to leverage the scientific (health economics) expertise necessary to push for reduced pricing. When the challenge was simply gaining access to needed medications for their members (i.e., reimbursement on drug plans), the actual cost of the drug was a secondary or subsidiary consideration.

While the CPC is constantly urging the INESSS and health insurers to make concessions on the price of anticancer drugs, we found no evidence that it similarly calls on manufacturers to reduce those prices (33). Nor did we find any evidence of the CPC's denouncing the failure by the pharmaceutical industry to respect agreements with the Government of Quebec to ensure the lowest price paid in Canada (BAP rule: Best Available Price). Indeed, manufacturers concluded secret agreements with other provinces on the price of anticancer drugs, agreements that contravene the Quebec BAP rule (34).

A first step towards better management of conflict of interest is transparency and disclosure (35). The Association of the British Pharmaceutical Industry (ABPI) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) have codes of practice that require member companies to make public a list of organizations to which they provide support. The list must include the amount of financial assistance and a detailed description of non-financial support (36,37). In Canada, the Rx&D's "Guidelines for Transparency in Stakeholder Funding" recommend to members the disclosure, by means of their websites and annual reports, of all stakeholders to which they provide direct funding; but they do not require disclosure of the value of the support. The Rx&D code is voluntary, but membership in the organization requires companies to abide by the code (38). There is no equivalent to the ABPI or EFPIA for patient interest groups that sets standards of practice or offers guidelines for this community.

A UK study found that only 26% of the 246 patient advocacy groups receiving funding from the industry declare such information on their website: 22 groups name companies, 18 provide information on the type of activity funded, 14 on the amounts and 4 on the portion of their budget coming from industry (18). Ball and colleagues (8) analyzed 69 websites of national and international patient organizations based in the United States, the United Kingdom, Australia, Canada and South Africa, and found that only one-third specified the source of their funding and the donor's name, but without necessarily specifying the amount of funding. Similarly, Rothman and colleagues (17) found that among 161 US groups receiving funding from Eli Lilly, 25% reported receiving funding from this manufacturer and 10% stated the use of funds, but none disclosed the amounts received.

On the disclosure of funding sources, the practices of CPC are minimal. On its website, the group provides a list of pharmaceutical industry donors but without specifying the amounts

or the use of donations; nor does the CPC provide a public annual report. However, for some specific activities, donors' logos appear on official documents ("états généraux," national conferences; "cahiers spéciaux"). The CPC website states that "[f]inancial contributions of our partners, whether from public institutions or private companies, are governed by a Policy on Partnerships from the Board of Directors of the Coalition and prevents any interference in the Coalition's governance" (39). And as quoted in an article in Le Devoir, according to the spokesman for the CPC, "[t]he Coalition does not depend on pharmaceutical companies in its decision-making" (D.2011.12.03). But no details concerning the Policy on Partnerships are given, nor is the policy available online. This omission clearly raises important questions. Even if industry donors are not directly involved in a group's decision-making processes — especially if the percentage of operating funds that come from industry is substantial — one can reasonably question whether the group is actually able to make decisions or take positions that go against the interests of their major donors.

Conclusion

Patient interest or advocacy groups play a significant role in raising awareness about specific illnesses, in supporting patients and in contributing to decision-making about the development and financing of new and existing drugs. In order to play this role effectively, these groups need financial support. In the context of scarce public resources, these groups have increasingly turned to the private sector for financing. With 60% of its funding coming from the pharmaceutical industry, the CPC is an example of a group that is particularly vulnerable to influence.

The interests of patients and industry can converge on issues related to the approval and reimbursement of medications. But even on issues of drug reimbursement, these interests do not always align perfectly. From our analysis and based on the available information, the CPC's commitment to its patient-members does not appear to be optimal on a number of different occasions. For example, the absence of a clear position or warning against Avastin for breast cancer raises some serious questions about the agency's role as a watchdog or source of reliable advice to its patient community. Moreover, the CPC's focus on the issue of reimbursement of expensive, low-efficiency drugs also raises questions, because such reimbursement has an important opportunity cost and does not appear to be the best way to use scarce resources to fight cancer. Finally, we found no evidence that the CPC has called for manufacturers to reduce prices, or lobbied the Quebec government to negotiate for lower drug prices, as do other provinces. Similarly, we found no evidence that the CPC has denounced the failure by the industry to respect agreements with the Quebec government in ensuring the lowest price paid in Canada.

In order for patient interest groups to manage the problematic financial COI in which they find themselves when they take funding from the private sector (e.g., pharmaceutical or medical device industries), these groups should be, at a minimum, required to disclose donors' names publicly, as well as the amount, the nature and the use of the support they receive from public or private donors. They should also include details of COI of any advisers to the group, and disclosure material needs to be prominent and accessible. Furthermore, general donation should be preferred, and specific funding of activities discouraged, in order to limit the capacity of donors to subtly orient the groups' activities. Above all, more public funding would make advocacy groups less dependent on private industry sources. But in the current economic context of reduced public funding to patient interest groups, and given the evident difficulty in funding activities through individual private donations, many groups will choose to turn to the private sector for support. It then becomes essential that patient

interest groups aim at full transparency regarding their fundraising activities, their operating budgets and their governance policies if they are to protect the trust that they have developed with their members and civil society. Such transparency would enable appropriate public scrutiny on the functioning of interest groups, making them less effective vectors of industry messages and thus less open to and less interesting for manipulation. Finally, an increased role for advocacy groups without industry funding may help to make debate about drug reimbursement and eventual policy decisions more credible and accountable.

Limitations

This study has several limitations. First, the information on CPC is limited to what was publicly available on the Internet and in the newspapers. For example, a spokesperson of the group mentioned that its relations with donors are regulated by a Policy of Partnership, but we did not contact CPC to obtain this document and so did not include it in our analysis. This approach reflects our normative stance that such information should be public and easily accessible if a group is to be both transparent and thus accountable. Second, our study did not allow us to make causal inferences, although we could nonetheless draw reasonable conclusions from the associations between company sponsorship and group positions and actions. Finally, while a case study does not allow any generalization to the practice of other patient groups, it does point to important issues of concern that are generalizable.

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Accessibility and transparency of editor conflicts of interest policy instruments in medical journals

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Original version: Smith E, Potvin M-J, Williams-Jones B. Accessibility and transparency of editor conflicts of interest policy instruments in medical journals. Journal of Medical Ethics. 2012;38(11):679-84.

Abstract

Background: There has been significant discussion about the need to manage conflict of interest (COI) in medical journals. This has led many journals to implement policies to manage COI for authors and reviewers; however, surprisingly little attention has been focused on the COI of journal editors.

Objective: The goal of this exploratory study was to determine whether the policies were accessible to the public and to researchers, and to discuss the potential impact on public transparency.

Design: The authors conducted an internet search of editor COI policy instruments that have been developed, implemented and communicated by the top 10 peer-reviewed medical journals (2010 ISI Web of Knowledge Impact Factor), and assessed their general accessibility by gauging the level of difficulty in navigating the journal's website (number of clicks to find the policy instruments).

Results: Only four of the 10 medical journals (40%) in this study have accessible COI policy directives that include editors (JIM, PLoS Medicine, AIM, CMAJ). One journal (NEJM) had an editorial on the subject, and another (The Lancet) mentioned editor COI in their general guidelines. These documents are not readily accessible; starting from the journal's main website at least four clicks are needed to access these documents.

Conclusion: These results suggest that there is a general lack of accessible editor COI policy instruments among leading medical journals, something that may consequently have a negative impact on the trust accorded to these journals.

Acknowledgements

The authors would like to thank Ghislaine Mathieu, Zubin Master, and the anonymous reviewers for their invaluable comments and suggestions on this manuscript, and Camille Assémat for her help with preliminary data collection. Many of the ideas in this paper were benefited from the ongoing critique by, and discussions with, the Conflict-of-Interest Research Group.

Introduction

As relationships and arrangements between universities and industry continue to flourish, conflict of interest (COI) has emerged as a topic of growing interest in the media and in academic circles. With respect to publication practices, discussions regarding COI typically focus on authors and peer-reviewers (1). However, journal editors may also experience COI situations when their interests — be they financial, personal, ideological or institutional — influence their primary obligations and duties. Notably, editors have a duty to ensure the integrity of the review process, and in so doing, contribute to an appropriate level of

objectivity and impartiality in scientific publishing. A journal's high standard of integrity provides its readership (academics, health professionals and the public) with an increased level of assurance as to the veracity and reliability of published findings.

Conversely, any compromise that undermines a journal's integrity would impact its standing and could raise doubts in the minds of diverse stakeholders about the very process of scientific research and publishing.

In the medical literature, COI can be defined:

> [...] as existing when an individual or institution has a secondary interest (e.g., an ownership interest in a start-up biotechnology company) that creates a risk of undue influence on decisions or actions affecting a primary interest (e.g., the conduct of objective and trustworthy medical research) (2).

For example, an editor may decide to publish and promote a friend's or family member's manuscript while downplaying or ignoring criticisms raised by peer-reviewers. Conversely, an editor — who also conducts academic research — might refuse to publish a competitor's manuscript. Editors are often responsible for choosing peer-reviewers and may choose individuals with particular scientific perspectives that reflect a narrowly focused or biased ideology. Editors may have significant financial interests (e.g., with pharmaceutical or medical device companies) that may influence their decision to publish or reject a manuscript. Editors may have the financial viability of their journal in mind when choosing which manuscripts to publish; consequently, they may decide to accept and produce press releases for particularly 'news-worthy' or 'sensational' articles in order to increase popularity, and thus subscriptions and article sales (3). However, the newsworthy article that sells well may lack a sufficiently robust methodology or might not present any real scientific advance or contribution to knowledge. Even if they are completely reliable, these newsworthy articles should not benefit from special treatment when compared with other equally respectable works from less high-profile scholars or on less sensational or appealing topics. The tension between financial viability and academic objectivity is inevitable in a business such as medical publishing, especially with the move towards open access publishing and ongoing experimentation with the journal business model. Even in publishing houses where the owner has financial responsibility and the editor is provided considerable independence, tensions are likely still present, and conflicts can thus arise between owner and editor. The outcomes of such editor COI are manifold and may include lack of integrity in the review process, diminished reputation of the journal and limited objectivity and impartiality in the presentation of research findings. In the longer term, this could negatively impact the well-being of patients and the community.

The aforementioned definition of COI is relatively broad, and thus the examples of editor COI will be diverse in scope and severity. Since these COI may not all be serious at all times, it may be impossible to know their potential negative consequences outside of a specific context. Potential risks and consequences of diverse forms of COI — including but not limited to financial or professional COI — should be considered in order for journals to determine the most appropriate responses or preventive measures. But the challenge will be in recognising and accepting that neither professional integrity nor a declaration of COI is sufficient to overcome the diversity of COI that arises in academic publishing (or in research more generally). Other activities including, for example, awareness raising and ongoing discussions among the editorial team and the wider academic community will be essential. Although journal editors have been less scrutinised than authors with regard to COI, editors

should not be any less concerned or diligent in their management. By promoting the establishment and effective communication of editor COI policies, editors can be proactive in reducing the risk of academic scandals. The scientific community has already suffered greatly from such scandals; editors can and should take the initiative to prevent academic misconduct for their own good standing as well as that of the general medical research community.

Many organisations, such as the International Committee of Medical Journal Editors (ICMJE), the Committee on Publication Ethics (COPE) and the World Association of Medical Editors (WAME) promote the adoption of COI policies for authors, peer-reviewers and editors (4-6). A policy can be important in setting out general principles or values (e.g., transparency, integrity, accountability) and in managing COI by setting out clear processes (e.g., through avoidance, recusal or disclosure). However, as Elliot notes (7), it may be impractical or unrealistic for a policy to address all potential COI situations, and management plans cannot be realistically expected to address every possible way that COI can influence scientific judgment. Further, the effectiveness of disclosure processes (one of the most common methods used in policies for managing the wide range of COI) has been challenged in recent psychological and economic research (7) raising serious concerns about the effectiveness of current processes. Nevertheless, once the limitations of a policy and associated processes are clearly understood, complementary tools and strategies (e.g., conflict management, education) can be brought to bear to promote better awareness about COI in publishing and thereby ensure the ethical management of situations that could undermine trust in a journal.

In considering the objectives of various policy statements on COI for authors and/or peer-reviewers, it would seem reasonable that editors should also be included since they play an important role in, and have a measure of accountability for, the integrity of medical publication (8). An examination of 10 leading medical journals demonstrates that when editor COI policy instruments are available, they are not sufficiently accessible. This deficiency will be discussed with relation to the rationales of organisations such as ICMJE, COPE and WAME in promoting COI policies for editors. We conclude with a discussion of the importance of accessibility and transparency of editor COI policy instruments in supporting the integrity and credibility of medical journals.

Background: Managing Editor Conflict of Interest

As previously mentioned, international and national organisations have been established to develop and promote policies that address issues of research ethics and scientific integrity. These include, but are not limited to, diverse policies dealing with the management of COI. For example, the ICMJE has a COI policy — *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Conflicts of Interest* (9) — that promotes disclosure of the COI of authors (or the authors' institution), reviewers and editors. There is a specific section on disclosure (and recusal when warranted) intended for editors and editorial staff. Another prominent organisation is COPE, which, in its *Best Practice Guidelines for Journal Editors* (10), makes two main recommendations regarding the management of editor COI: 1) "publish lists of relevant interests (financial, academic and other kinds) of all editorial staff and members of editorial boards (which should be updated at least annually)" and 2) "adopt suitable policies for handling submissions from themselves, employees or members of the editorial board to ensure unbiased review (and have these set out in writing)." Similarly, WAME promotes the implementation of COI policies for authors, reviewers and editors in their policy framework, *Conflict of Interest in Peer-Reviewed Medical Journals* (11), which stipulates that COI

guidelines should be made publicly available through publication. WAME also has a specific policy for editors called *The Relationship Between Journal Editors-in-Chief and Owners* (12) that outlines the general responsibility and procedures to limit COI between editors and journal owners.

In response to these prominent recommendations, medical journals have adopted various types of COI policy instrument for editors, often derived from the ICMJE, WAME or COPE guidelines. Three empirical studies give some evidence of the prevalence of such policies. In 2004, Haivas and colleagues found that while 63% of respondent editors of medical journals considered the declaration of editors' financial COI to be important or very important, only 30% of journals had an explicit policy to deal with editors' financial COI (13). In 2006, Cooper and colleagues found that only 39.6% of journals reported having editor policies on COI (14). In 2007, Ancker and Flanagin published a comparison of the COI policies of 84 peer-reviewed journals from 12 different scientific disciplines, including biomedicine; they found that only 56% declared having policies on editor COI (15). A quick comparison of the results of these three studies has obvious methodological limitations due to different sampling and survey methods. Nonetheless, it is still reasonable to presume that there has been an improvement in the implementation of editor-related COI policy instruments for medical journals in recent years (15). While this may be a measure of progress, there is still significant work to be done to promote and implement policy instruments and raise awareness across the medical and broader academic communities.

Studies of authors' COI policies have shown that clarity and content (16,17) are important factors to consider in developing and implementing COI policy instruments. As well, the availability and coherence of policy instruments are critical. In the above-mentioned empirical studies, it was noted that policy statements were not always readily available on journal websites. The editors surveyed in these studies were also asked about their individual journal COI policies, guidelines and practices, which in some cases were not formally developed or publicly accessible. In effect, these policy instruments reflect the often-informal consensus of a narrow or limited constituency (staff and stakeholders of an individual journal) regarding COI declaration or internal procedures (how COI is managed, e.g., recusal); there is no common format or content to these individual policy statements across medical journals. Further, these policy instruments may be amended or abandoned at the discretion of new ownership, management or membership of editorial boards. Policies and practices regarding editors and their staff are far from being consistently applied (18). Accountability for the development and implementation of editor COI policy instruments is, for the most part, narrowly restricted within the journal or organisation.

Our exploratory study used a different method to consider whether editor COI policies are generally accessible to the public and to researchers. That is, we examined whether policies were publicised or at least publicly accessible on journal websites; this is important to consider because as in the case of other organisation (12), written, publicly disclosed and accessible COI policies can be an important means of fostering credibility and trust in the scientific publishing enterprise.

Methods

We conducted an online search (June-July 2011) of the top 10 peer-reviewed medical journal websites — according to ISI 2010 Impact Factors — to identify journals that had COI policy instruments that explicitly mentioned editors (Table 1). We selected the top 10 medical journals because they are often cited as examples to illustrate trends in scientific medical

publishing (15). Further, journals with higher impact factors are more likely to have policies (13) because they are more often scrutinised by the academic community and the public. Nonetheless, smaller or more focused journals also likely encounter problematic COI (e.g., everyone knows each other), and so could provide good samples to explore in future studies on editorial COI.

Table 1. Editor COI policies of top 10 peer-reviewed medical journals, 2010

#	Journal	Formal editor COI policy directives	Editor tools or best practices	Public declaration of editor COI	Links
1	*New England Journal of Medicine (NEJM)*	NA	Editorial: 'Sponsorship, authorship and accountability', NEJM, 345(11): 825–827[24]	Declaration 'None of the NEJM editors has any financial relationship with any biomedical company' http://www.nejm.org/page/media-center/integrity-safeguards[25]	ICMJE
2	*The Lancet*	NA	In the document entitled 'Information to authors' there is a link to the ICMJE uniform requirements for manuscripts submitted to biomedical journals, writing and editing for biomedical publications, and the COPE code of conduct	NA	ICMJE, COPE
3	*Journal of the American Medical Association (JAMA)*	'Conflict of Interest Statement for JAMA and Archives Journals Editorial Staff' http://jama.ama-assn.org/site/misc/coistatement.xhtml[20]		NA	ICMJE
4	*Annals of Internal Medicine*	'Conflict of Interest: Definition and policy' http://www.annals.org/site/misc/ifora.xhtml[21]		NA	ICMJE
5	*British Medical Journal*	NA	NA	Yes	ICMJ, COPE, WAME
6	*PLoS Medicine*	'PLoS policy on declaration and evaluation of competing interests' http://www.plosmedicine.org/static/competing.action[22]	NA	Yes	ICMJ, COPE
7	*Annual Review of Medicine*	NA	NA	NA	NA
8	*Archives of Internal Medicine*	NA	NA	NA	ICMJE
9	*Canadian Medical Association Journal*	'Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication' http://www.cmaj.ca/authors/policies.dtl[23]		NA	ICMJE
10	*Journal of Internal Medicine*	NA	NA	NA	ICMJE

Journal list compiled from the 2010 ISI Web of Knowledge journal ranking by impact factor. COI, conflict of interest; COPE, Committee on Publication Ethics; ICMJE, International Committee of Medical Journal Editors; NA, not available; WAME, World Association of Medical Editors.

For the purposes of our study, policy instruments can be grouped into two categories, as follows.

Policy directives

These typically state an objective, key principles and mandatory procedures. The higher-level policy directives are often formal, generic statements applied and available to a large constituency; however, there may also be directives with a narrower scope designed specifically for a smaller constituency (one journal or institution).

Tools and best practices

These are not policies per se, but rather ways or approaches developed by practitioners to address issues and meet policy requirements. Recommended tools or best practices are typically the result of trial-and-error, innovation and problem solving.

We decided to use these two categories because of the diversity of COI policy instruments that could be used to manage editor COI. These distinctions were not made in the previously mentioned studies, where all policy instruments were treated as similar.

To verify whether editor COI policies are made generally accessible and easy to find for the public and researchers, we navigated journal websites for policies, guidelines or disclosures that might apply to editors. Since accessibility (and thus public transparency) was our main

issue of concern, we did not consider the private intranet pages (sites that are only accessible to journal editors and usually password protected); we considered only publicly accessible extranet pages. The search was conducted by an individual experienced in searching for policies in academic journals, that is, not a novice or 'uniformed' viewer. All searches started on the journal's main website. The number of 'clicks' to different menu items or web pages were then counted to see how readily accessible these policies were in practice (Table 2); the number of clicks is an approximate metric for the amount of time and effort required to find relevant COI policies. We also took into consideration and noted any affiliation or association of the journal to organisations that promote the management of editor COI, such as the ICMJE, WAME and COPE.

Table 2. Accessibility of editor COI policies of top 10 peer-reviewed medical journals, 2010

#	Journal	Website accessibility
1	*New England Journal of Medicine*	http://www.nejm.org Click on 'for authors' Click on 'editorial policies' Click on 'sponsorship, authorship, and accountability'
2	*The Lancet*	http://www.thelancet.com Click on 'information for authors' Scroll down, at the bottom of page click on 'Download a PDF version of the full guidelines for authors of The Lancet.' On the first page of this document in the left margin click on the link to the ICMJE or COPE documents
3	*Journal of the American Medical Association* (*JAMA*)	http://jama.ama-assn.org Click on 'for authors' Click on 'JAMA editorial policies' Click on 'conflict of interest' Conflict of interest statement for JAMA and archives journals editorial staff
4	*Annals of Internal Medicine*	http://www.annals.org Click on 'information for authors' in the right margin Click on 'information for authors' in main list Substantial information on editors COI is available in the section 'Conflict of interest: definition and policy'
5	*British Medical Journal*	NA
6	*PLoS Medicine*	http://www.plosmedicine.org Click on 'for authors and reviewers' Click on 'editorial and publishing policies' Click 'competing interests policy'
7	*Annual Review of Medicine*	NA
8	*Archives of Internal Medicine*	NA
9	*Canadian Medical Association Journal* (*CMAJ*)	http://www.cmaj.ca Click on 'information for authors' Click on *CMAJ* 'editorial policies' In the section 'conflict of interest' there is a large section on editor COI
10	*Journal of Internal Medicine*	NA

COI, conflict of interest; COPE, Committee on Publication Ethics; ICMJE, International Committee of Medical Journal Editors; NA, not available.

Results: Managing Editor COI

Although previous studies suggested an increase in the prevalence of editor COI policy directives, guidelines and practices, our study found that these instruments are often not easily accessible on individual journal websites. Only four of the 10 journals in our study (40%) have a policy that includes editors, namely, the *Journal of Internal Medicine*, *PLoS Medicine*, *Annals of Internal Medicine* and the *Canadian Medical Association Journal*. The *New England Journal of Medicine* has an editorial on the subject (but it is very limited and not readily accessible), and *The Lancet* mentions editor COI in their general guidelines (Table 1). It should also be noted that accessing these documents (Table 2) requires an individual to make at least four clicks starting from the journal's main website; this rather involved or complicated navigating can take considerable time and effort and certainly does not make editor COI policies easily accessible.

For the journals where we could not find an editor COI policy, these were often affiliated to ICMJE or/and COPE, and by their association they may adopt the relevant policies of these

organisations. For example, COPE's *Code of Conduct for Editors* states that "Editors should have systems for managing their own conflicts of interest as well as those of their staff, authors, reviewers and editorial board members", and best practices should include publishing a list of 'relevant interests' of all editorial staff and members (6). While association with such organisations may give the impression that COI is being addressed — and so potentially increasing a journal's prestige — everyone is aware of the COPE or ICMJE policies. Making editorial policies accessible, alongside reference to COPE and ICMJE affiliation, would be a more transparent method of managing COI. Interestingly, none of the journals in our study had any links to their publishers' COI policies. For example, Elsevier — which publishes *The Lancet* — has an online ethics resource to support journal editors called the Publishing Ethics Resource Kit (26). Included there is a short policy that mentions editor-specific COI, for example, "Unpublished materials disclosed in a submitted manuscript must not be used in an editor's own research without the express written consent of the author." (27)

In addition to the previous data on the presence and accessibility of policy instruments in medical journals, there were certain noteworthy differences in the form, content and disclosure of editorial COI policy instruments. While they are classified in the table as either 'formal policy directives' or 'editor tools or best practices', the policy instruments inside each category are quite heterogeneous. Certain COI guidelines, such as those of the *Annals of Internal Medicine*, include editor considerations in their general COI policy applied to authors; that is, all COI should be disclosed, but it is not clear what procedures should follow after disclosure. *PLoS Medicine*, for its part, has a policy with information for all parties involved in the publishing process, including specific subsections that apply to editors. These sections specify, for example, the possibility of recusal for an editor who is in a COI. As already mentioned, if some journals such as the *Journal of the American Medical Association* (JAMA) and *The Lancet* do not have publicly accessible editor COI policy directives or guidelines, they do publicly (on their websites) subscribe to the ICMJE's guidelines 'Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication', which include subsections dealing with COI for editors, authors and peer-reviewers. The CMAJ, one of the founding member organisations of the ICMJE, has adopted this policy as well. JAMA has a specific policy that applies exclusively to journal editorial staff; its goal is to 'minimize the influence of conflict of interest on all aspects of manuscript submission, review, and publication' and discusses various ways to manage editor COI, including disclosure, recusal and the listing of potential COI to raise awareness.

Two journals — *PLoS Medicine* and the *British Medical Journal (BMJ)* — a make a practice of disclosing specific editors' interests on their websites. These disclosures are typically of a financial nature, namely, reimbursements for attending symposiums, speakers' honoraria, fees for organising educational events, funds for research, funds for staff and consulting fees. However, there is also a section that outlines non-financial COI, such as editors' ties to particular research groups and universities, and links to charities or non-profit organisations. Editor association with specific individuals or groups reveal personal ties with individuals while links to charities and non-profit organisations could indicate potential ideological or religious interests, influences or biases. Moreover, the *New England Journal of Medicine* provides a declaration stating that their editors do not have any financial relationships with a biomedical company. While this declaration can give a certain level of transparency regarding specific financial COI, it does not mention all editors' interests, like in the case of *PLoS Medicine* and *BMJ*. While *BMJ* takes this strong approach of disclosing their editors' interests, they do not publish or advocate a specific policy promoting COI management

practices. It would appear that the management of COI is an internal practice and not a procedure that results from any formal and transparent policy.

Discussion

The results of this online exploratory study contrast with other empirical studies that use survey methods. Studies using survey methods that asked editors directly about their journal's COI policies included internal practices that are not necessarily widely accessible or commonly available to researchers or the general public (e.g., internal policies or practices). Our research focused on the public internet accessibility of policies or guidelines, an approach that we suggest provides more attention to the level of transparency that journals enact regarding their management of editor COI. Our results show that individuals looking for information on journal websites about editor COI — even at the highest-ranking medical journals — may not find relevant or useful policy directives, guidelines or procedures. In many instances, navigating the website to locate a specific policy instrument is complicated, time-consuming, and not user-friendly. If a policy is linked on a site but is buried many layers deep and hard to find, it is not 'accessible' in any meaningful sense. So, if one agrees with our premise that accessible COI policies foster transparency and trust in institutions or organisations — including medical journals (28) — one can conclude that there is inadequate transparency regarding policy instruments to manage editor COI.

Why is there so little transparency about editor COI, especially when authors are, more than ever, held to much higher standards? (29) Although there is clearly still room for improvement, there has been significant progress over the past decade in the implementation of policies to manage author COI (30) which, we argue, may guide the development of editor COI policies.

More accessible editor COI policy instruments will contribute to enhancing the reputation as well as the accountability and overall integrity of medical journals. The availability of transparent COI management guidelines and procedures in the literature on COI in medicine fosters public confidence and trust in the medical establishment (28). This is important since public opinion of the medical community has been negatively affected by controversial COI situations (31). Medical journal editors are part of the medical research community and can have a positive role in the way COI is managed and the subsequent impact on public opinion. Transparency and accessibility can promote greater accountability on the part of all stakeholders involved in the publishing business. Since editors are accountable, they have a professional duty to actively engage in managing COI to maintain the reputation of research and publication.

Conclusion and Recommendations

Through this modest study, we have shown that editor COI policies for 10 of the most respected international medical journals are difficult to access by even experienced researchers, and thus likely opaque to the general public and scientific community; in some cases, no policies were accessible which can raise doubts about their very existence. Considering that the journals in our study are high profile — that is, top 10 by ISI Impact Factor — they can be reasonably expected to have robust editorial policies, including those that address COI for authors and editors. But this assumption is insufficient. For example, even though the major biomedical publishers such as Elsevier or Wiley-Blackwell pledge adherence to COPE's Code of Conduct, only three of the 'Top 10' (i.e., *BMJ*, *The Lancet*, *JIM*) are published by such companies (*PLoS* is an independent member of COPE); the medical association journals thus appear to be lagging behind the commercial sector in this respect.

The difficulty (or impossibility) in accessing editor COI policies may limit the transparency of these journals in demonstrating that their editorial review and publication meet the highest standards of quality and objectivity, and consequently have the potential to impact negatively the public's trust. In this context, we recommend development, by the medical editorial community, of robust COI policy instruments and tools. Organisations such as the ICMJE, COPE or WAME should provide direction and guidance regarding editorial COI relevant to specific journals. Policies similar to the one promoted by WAME, for example, offer a useful starting point for dealing with the relationship, and possible COI, between journal editors-in-chief and owners of the journal (12). The availability of more detailed policy provisions intended to clarify and influence desired editorial behaviour (roles and responsibilities) will promote greater transparency; a good starting point is the Council of Scientific Editors' *White Paper on Promoting Integrity in Scientific Journal Publications* (32). The homepage of the journal should have a standalone section regarding editorial policies to provide for greater public ease of access.

We also recommend continuous editor education regarding COI. Typically, editors are selected for their research competencies rather than for their editing experience; they may not have knowledge about editorial ethics. As such, we believe that editors may be exposed to potential COI situations that they are ill-equipped to recognise and manage; therefore, we advocate for compulsory training with regard to the identification and management of editor COI. ICMJE, WAME and COPE, for example, could also reflect collaboratively upon editor COI and make these reflections widely available and updated through easily accessible online tools. Moreover, it would be of interest to further promote tools that publishers already have available, such as Elsevier's 'Publishing Ethics Resource Kit', Wiley-Blackwell's list of extensive practice guidelines on publication ethics (33), and COPE's very practical guidelines, e-learning modules, cases and flowcharts (34). This would go a long way to helping medical journals implement transparent and accessible editor COI policies, and so reinforce the respect and trust in these organisations.

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Barriers to research on research ethics review and conflicts of interest

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Original version: Williams-Jones B, Potvin M-J, Mathieu G, Smith E. Barriers to research on research ethics review and conflicts of interest. IRB: Ethics & Human Research. 2013;35(5):14-20.

Note

This paper presents the experience of a research team submitting their project for ethics review as part of a multicenter review process, thus we have anonymized the name of this Research Ethics Board. Our study was also initially reviewed and approved (prior to engaging in the multicenter process) by the Research Ethics Board of the Faculty of Medicine (CERFM) at the Université de Montréal. All authors participated in the writing of this manuscript and read and approved the final version.

Acknowledgments

We would like to thank Zubin Master for helpful comments on an early draft of this manuscript. Many of the ideas presented in this paper benefited from ongoing critique and discussion with the Conflict-of-Interest Re- search Group at the Université de Montréal. Potvin was supported by scholarships from the Centre de recherche en éthique de l'Université de Montréal (CREUM) and the Faculty of Medecine; Mathieu was supported by a scholarship from the Centre interuniversitaire de recherche sur la science et la technologie (CIRST); and Smith was supported by Masters and Doctoral Fellowships from the Social Sciences and Humanities Research Council of Canada (SSHRC) and a J.A. DeSève Scholarship from the Université de Montréal. This research was supported by grants to Williams-Jones from the Fonds de recherche du Québec — Société et culture (FRQ-SC), and the Ethics Office of the Canadian Institutes of Health Research (CIHR).

Introduction

Research on research ethics — regarding both the governance and practice of the ethical review of human subjects research — has a tumultuous history in North America and Europe. Much of the academic literature focuses on issues to do with regulating the conduct and quality of ethics review of research protocols by ethics committees (research ethics boards (REBs) in Canada and institutional review boards (IRBs) in the United States) (1-3). In addition, some of the literature attends to issues particular to the review of qualitative research (4,5), and still other literature addresses the challenges posed by and the need for research on REBs/IRBs (6,7). It is this third group of literature within which our article is situated.

In 2009, we initiated an empirical bioethics project to advance REBs' understanding and management of conflicts of interest in their ethics review of research projects (8). The focus was REBs at Canadian universities, hospitals and medical research centers. Lo and Field define a conflict of interest as "existing when an individual or institution has a secondary interest (e.g., an ownership interest in a start-up biotechnology company) that creates a risk of undue influence on decisions or actions affecting a primary interest (e.g., the conduct of objective and trustworthy medical research)." (9) Our project was to involve 1) an analysis of the specific ethical challenges that conflicts of interest pose in REBs' review of health

research, and 2) the development and testing of practical model ethics guidelines to assist REBs in managing conflicts of interest. We set out to create a model that could be generalized across diverse institutional settings. Yet many REBs — often lacking a clear understanding of what constitutes a conflict of interest — did not consider themselves as being faced with conflicts of interest because "we don't review clinical trials involving the pharmaceutical industry." The result was that many REBs, especially those reviewing projects primarily in the social sciences, refused to participate in our study. Thus our second objective, that of building and testing a model guideline, was trans- formed into developing practical teaching tools to help REBs better *identify* and *manage* conflicts of interest when they review research projects.

Because we were interested in the experience of the REB as a group — not specifically of individual members — our plan to conduct interviews meant that an REB had to review and approve the proposed project. We obtained approval from one of the REBs at our university in early 2010. However, as we also wished to interview REBs in medical centers, we were obliged to submit our project through Canada's provincial multi-center process (also known as a multisite review). This necessitated a second full application to a central REB (which was based in a hospital), as well as to the dozen REBs we hoped to recruit as "participants" in our study. We were interested in learning from the experiences of REBs that dealt mainly with clinical research, from those that reviewed psychosocial, behavioral and public health research, as well as from REBs that re- viewed non-health related research. This second review process proved much more complicated and time consuming. Moreover, it involved unduly demanding and inappropriate requests due to 1) an apparent "clinical trial bias" on the part of some REBs (i.e., a bias against qualitative research based on the view that all research projects require the same level of risk analysis and protections as clinical trials), and 2) structural elements imposed by the multicenter process (e.g., substantial paperwork, requirement to have local respondents, and ethics review at all participating medical centers).

We eventually decided not to pursue the multicenter process and so continued our interviews with a limited number of REBs (less than five from the healthcare setting, a formal threshold under which multicenter approval is not required) that expressed an interest in participating in our study. In a detailed letter in early 2011 to the central REB that had reviewed our project, and to all the participating REBs at healthcare institutions, we explained the reasons for our decision to withdraw from the multicenter review process. Our hope was that the letter — which led to writing this article — might help to further the dialogue on ways to improve the multicenter review process. More specifically, we wished to highlight how projects considered as minimal risk according to the new *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2) (10) — Canada's principle research ethics framework — were inappropriately treated with as much scrutiny and concern as would be projects that present a high risk to participants; the result is that the current review process is not conducive to certain types of qualitative and empirical bioethics research. Following Article 2.7 of the TCPS2, REBs "should adopt a proportionate approach to ethics review, based on the principle that as the risk to participants increases, so should the level of scrutiny in assessing the research and the level of expertise involved in the review process." (10)

As ethicists exploring issues in research ethics, this experience, while frustrating, was also a useful source of practical information. It reinforced our conviction that REBs are placed in a difficult situation, and so while they need better support and training to carry out their very important work of ensuring that research involving humans meets the highest ethical standards, they also need a more coherent and supportive governance system. This article is

thus not meant as a condemnation of the REBs with whom we interacted in the ethics review process (or of REBs in general), but as a reflection on the challenges facing these committees and the need for continued training about conflicts of interest, about what constitutes risky versus minimal risk research, and about the appropriate evaluation of projects that employ qualitative research methods in a health sciences context.

Conflicts of Interest, Vulnerability and Risk

From the start of our project, we recognized that what we were proposing was rather unique. The REBs that would review our project — and thus their members — would also be the subject of research, and this was not trivial nor without consequence. As we stated in our recruitment letter *"We realize that asking you to both review and consider participating in our project places you in an awkward conflict of roles (i.e., reviewer and participant). Nonetheless, we hope that in recognising this tension — and the importance (and challenge!) of dealing with COI more generally — you will be favourably inclined to accept and agree to participate in our study."* But once we received their comments and recommendations, we quickly recognized that the REBs in the multicenter process had rarely dealt with our type of project (empirical bioethics), or the particular conflicts of interest that we had explicitly named and defined.

Whose Interests and What Risks?

One of the primary responsibilities and interests of an REB is to evaluate the risks and benefits to participants of a given research project. But when REBs are themselves the potential participants, they may have other primary interests in participating in a study (that would be secondary interests when viewed from their role as REB members), such as being individually interested or in favor of the study or uninterested because the study would involve too much work. Equally, because we were soliciting REB participation as a whole — and not that of specific members — some REB members might have found it difficult to separate their individual (member) and collective (REB) interests.

The conflicts of interest that the REBs were likely most familiar with, and which probably shaped their review of our project, include 1) those in which an REB member has a conflict due to their involvement with a project under review, or 2) those that arise in the clinical research setting (whether involving physical or psychosocial care) (11), such as financial ties or personal relationships that can negatively affect clinician-researcher objectivity. In these cases, the selection of other evaluators (i.e., recusal from decision-making) or research participants without any conflict of interest would be an appropriate way to ensure objectivity and to protect vulnerable populations, such as patients. A similar approach was used to evaluate our project; that is, we were told that the project must include impartial evaluators who were in no way involved or participating in our project, thereby excluding participation of the REBs.

Our view was that while the evaluators would also be research participants in the context of our research, they did not share the same vulnerability as participants in clinical trials and thus did not require a similar level of protection. REB members are invariably highly educated competent adults who are tasked with assessing the ethics of research projects; they do not demonstrate the specific vulnerabilities of patient participants or minority groups (e.g., being ill, in need of treatment, or subject to a strong power relationship with the investigator), because they are not at any grave risk of physical or psychosocial harm. Nor is the ability of REB members to give free and informed consent compromised. The questions we hoped to ask them were not in any way sensitive, because we were not interested in particular cases of conflicts of interest (or possible misconduct) that might put the REB in a

difficult position with regard to their institution. Instead, we wanted to know 1) how and what they would define as a conflict of interest, 2) whether their institution had relevant/useful policies or guidelines about conflicts of interest, 3) their experience (if any) with and management of conflicts of interest, 4) their view of the role of ethics committees in a situation involving a conflict of interest, and 5) what major ethical issues or dilemmas they encountered with regard to conflicts of interest.

As a side note, the TCPS2 has specific text that makes clear that participant vulnerability alone should not be grounds for exclusion from research: "Individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances." (10) The rationale is that if vulnerable populations (such as women, children, the elderly, minority communities) are prohibited from participating in research because of their vulnerabilities, they can then never benefit from the results of research (as do other groups), thereby reinforcing their vulnerability.

The ethics review of our proposed project overestimated the actual risk to which REBs as participants might be exposed because standards for protecting patient participants involved in clinical trials were used, and because the review did not take into consideration the existence (or not) of vulnerabilities that would legitimately preclude participation in research, and thus neglected the contextual elements of our study. The specific elements that did pose risks were mainly confidentiality and autonomy, which were managed through standard ethical research procedures to ensure anonymity and informed consent of participating REBs, and thus their members.

Which Management Procedures?

Our proposed project raised a number of conflicts of interest, of that there was no doubt. But the problematic conflicts were primarily those to do with REBs' role in reviewing the project:

- The role conflict of the in-house respondent (a local collaborator, something imposed by the provincial multicenter process), i.e., chairs of the REBs, meant that this person would be a putative research team member, participant and reviewer;
- The role conflict of the principal investigator (PI), who is also a member of the University Committee on Research Ethics which has an oversight function with regards to affiliated health institutions' REBs;
- The conflict of roles for REB members who would be both reviewers and research participants.

The multicenter process required us to identify, up front, institutional respondents/collaborators from the contexts where we would be conducting our study, even though these individuals were not involved in the conduct of the research. We understand that this requirement may be an important safeguard in the context of clinical trials, i.e., by ensuring that there is a local research collaborator involved in any trial conducted in the institution. However, this requirement was entirely inappropriate, and even unethical in the context of our project, because it imposed a collaborator who was not a member of the research team nor in anyway active in the project. Should we include these respondents in all steps of the research (e.g., data collection, analysis, manuscript writing and editing)? Would their collaboration merit recognition through authorship on subsequent publications, even though they had little knowledge of research about conflicts of interest? How would we manage confidentiality with such collaborators? In order to complete the formal requirements imposed by the process, we had named as the key contact persons the chairs

or coordinators of the REBs who we hoped would participate. But it made no sense for them to be or to consider themselves to be collaborators on our project, which led to the inevitable confusion on the part of some REBs as to the roles of their REB chairs/ coordinators.

One of the solutions proposed by the evaluating REB to *avoid* some of these conflicts involved the *withdrawal* of the PI from major aspects of the project, specifically from reviewing any of the primary interview data. This proposal seemed inspired by an analytic framework proper to the context of clinical trials, where the issues of vulnerability of participants — and therefore the risks associated with conflicts of interest, namely bias — are significantly greater than was the case in our project. Also, if a conflict of interest can be resolved in certain circumstances by withdrawal or disclosure, these strategies are not always appropriate or effective (12). In the case of our project, transparency about our methodology coupled with a process of open discussion between the research team and REB members should have been sufficient to manage any conflicts of interest, while still protecting the integrity of research participants and the ethics review process. In fact, such an approach would have enabled the development of a relationship of mutual trust between the researchers and the REB members, while still ensuring a rigorous process of ethics review and continuous monitoring. In addition, it should have been noted by the REBs that, if at first glance, our project raised a number of conflicts of interest, they were not particularly risky or unmanageable. These conflicts of interest should have been the starting point for a dialogue between the research team and the REB members about how to appropriately identify, evaluate and manage conflicts of interest. As we have found in the other interviews conducted with REBs outside the multi-center process, the very act of participating in our study provided an opportunity — i.e., time — for this very sort of dialogue and learning about conflicts of interest, something that even the most conscientious REBs were hard pressed to do themselves given their very busy schedules and significant workloads.

Another important issue that was raised was potential bias of REBs as research participants. The evaluators of our proposed project argued that as the REB members had read the full proposal (including the letters of recruitment, methodology, and questionnaire), and since they would also be participants in our research, knowing our theoretical framework and hypothesis would bias their point of view, thereby undermining the objectivity and validity of our research findings. This issue was a particularly odd concern, and one that we were not at all expecting to be raised because of our research methodology and epistemological orientation. In our project, as in many qualitative traditions, subjectivity is a common reality, and even valorized because the intent is not to isolate the variables of a phenomenon under study (e.g., by controlling the conditions of data collection) as in many hypothetical-deductive studies in the quantitative tradition, but rather to encourage the emergence of a phenomenon's complexity through documentation of research participants' experience (13). It is the justification of the methodology and transparency of the research process that ensures the reliability of the research data (14-16). There was no question, in the context of our project, of formally testing a hypothesis; our aim was to develop an understanding of REB experience in order to support REBs in their review of research projects, and in particular, to help them identify and better manage conflicts of interest when these could not be avoided.

A final suggestion from the reviewers of our project was that we submit our proposal for ethics review to the Ethics Unit at the Ministry of Health to avoid certain conflicts of interest. This clearly illustrated the impasse faced by researchers conducting research on research ethics and REBs (17); we cannot submit proposals to an REB without generating conflicts of

interest. Even asking the Ethics Unit — which oversees the research ethics review process in the province (at least for REBs in the healthcare system) — to evaluate this type of project would be a conflict of interest because they have a vested interest in how research ethics is conducted in the province. In other words, regardless of where our project or others on the ethics of research ethics are evaluated, they will be subject to diverse sorts of conflicts of interest (e.g., an interest in the practices of specific REBs). This impasse confirms that it is imperative to continue such research so that REBs can better understand, identify and manage conflicts of interest. But how is such knowledge to be developed in the current context where REBs seem unable to fully understand the nature of conflicts of interest and how to manage them? Because they were scared of conflicts of interest and of the potential consequences of identifying them, many REBs took the safest route and refused to be participants in our ethics research study. In so doing, they undermined the possibility of conducting research for which they are the intended beneficiary, at least until better management of conflicts of interest becomes possible.

Possible Ways Forward

Unlike some pessimistic colleagues, we do not share the view that "research ethics is unnecessary and meddlesome bureaucracy that stifles research!" We are fully aware that REBs, whether in universities or in healthcare institutions, are working extremely hard with very limited financial and personnel resources, and are doing the best they can to protect research participants. There are, however, possible ways forward to improve the system currently in place. A good starting point to improve the ethics review of research projects in Canada would be for the provincial Ministries of Health, and the provincial and federal granting agencies, to be more cognizant of and responsive to the challenges encountered by some humanities and social science researchers in the process of research ethics review (18). In particular, these entities should pay heed to the TCPS2, which has an entire chapter on the ethics of qualitative research (Chapter 10).

It is also essential that a coordinated and efficient multicenter review process be implemented. Ideally, this would entail better management of multicenter research by testing different initiatives, such as reciprocal or centralized review. Reciprocal review involves agreements between different REBs to accept each other's reviews, while centralized review involves all participating REBs sending protocols to a centralized REB with demonstrated experience in conducting a specific type of review (usually in a field of research or on a specific topic). Such initiatives are being developed in the United States and in some Canadian provinces. In building the confidence between REBs (e.g., favoring dialogue) that would be necessary for better coordinated multi- center review, there would also be an opportunity to improve and facilitate knowledge sharing (19,20) about best practices, especially with regard to the evaluation of qualitative research and the identification and management of diverse forms of conflicts of interest (whether in the context of REB review or as part of the project under evaluation).

The fact remains that much work still has to be done in providing robust and accessible research ethics training for REB members in both clinical and university contexts. Training should focus on managing conflicts of interest, but also more generally on differences in research methodologies and traditions (21,22). While REB members come from different research contexts, they are specialists in the methodology of their own disciplines. As such, some methodological approaches may be misunderstood as being "soft" or lacking in scientific credibility. Such an ideological stance may even be a conflict of interest — because

of the interest in defending one particular perspective — and consequently has the potential to introduce bias in the ethics review of proposed projects.

The online training tools (tutorials, webinars) developed by the Interagency Panel on Research Ethics to explain the TCPS2 (10) — along with those developed by U.S. universities (23-25), the U.S. Institute of Medicine (9), or the University of Manitoba (26) — are excellent starting points. But these tools may still be insufficient. Even if REB members are fully versed in the TCPS2 and its guidance regarding conflicts of interest, multicenter review, minimal risk and proportional review, or the specificity and diversity of qualitative methods, their ability to implement such knowledge may be impeded by a lack of practical tools ("how, in practice do we deal with conflicts of interest?"), not to mention by structural or bureaucratic factors imposed by the provincial multicenter process (e.g., obligatory "local respondents"). What is necessary, then, is to find a way (e.g., through managing conflicts of interest and an external evaluation of them) for REBs to participate in ethics research on research ethics. By doing so, we will ensure that ethics researchers can develop the knowledge needed to create practical tools that can help REBs do their work better, something that our team is aiming to provide.

Conclusion

As researchers who conduct research on conflicts of interest and on research ethics more generally — and some of us are members of REBs — we clearly have a vested interest in seeing such research funded by the Canadian granting councils, and better understood (e.g., its particularities) and supported (e.g., education) by universities and healthcare institutions. But as researchers whose proposed projects undergo ethics review by REBs, we also have an interest in seeing REBs better resourced — both in terms of personnel and knowledge — so that they have the time to participate in research and ongoing learning, and thus are able to continue their work of ensuring that all research involving human participants meets the highest ethical standards. We would even go so far as to argue that REBs have a responsibility to be partners in research and continuing education about ethical issues such as conflicts of interest because research and education may help them improve the quality of the ethics review process.

In recounting our experience with issues about the ethics review of conflicts of interest research involving REBs as participants, we hope to have shown that substantial effort is still needed to sensitize the research ethics community to nuances in notions of vulnerability and risk, to the fact that not all research should be treated "just like clinical research," and to the importance of identifying and appropriately managing conflicts of interest that cannot or should not be avoided. Both REBs and ethics researchers must work to build mutual trust, which is necessary for any collaboration to succeed, whether it be for continuing ethics education or the conduct of ethics research. The current impasse facing research about REBs and conflicts of interest in the ethics review of research studies can thus be seen as an opportunity to engage in a constructive dialogue between all parties involved in research ethics — REB members, researchers, policy makers — which, after all, is part of what ethics is about.

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Managing antimicrobial resistance in food production: conflicts of interest and politics in the development of public health policy

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Original version: Williams-Jones B, Doizé B. Managing antimicrobial resistance in food production: conflicts of interest and politics in the development of public health policy. Les ateliers de l'ethique/The Ethics Forum. 2010;5(1):156-169.

Abstract

Antimicrobial resistance is a growing public health concern and is associated with the over- or inappropriate use of antimicrobials in both humans and agriculture. While there has been recognition of this problem on the part of agricultural and public health authorities, there has nonetheless been significant difficulty in translating policy recommendations into practical guidelines. In this paper, we examine the process of public health policy development in Quebec agriculture, with a focus on the case of pork production and the role of food animal veterinarians in policy making. We argue that a tendency to employ strictly techno-scientific risk analyses of antimicrobial use ignores the fundamental social, economic and political realities of key stakeholders and so limits the applicability of policy recommendations developed by government advisory groups. In particular, we suggest that veterinarians' personal and professional interests, and their ethical norms of practice, are key factors to both the problem of and the solution to the current over-reliance on antimicrobials in food production.

Acknowledgements

We thank Catherine Olivier for her helpful comments on an early draft of this paper. Béatrice Doizé was supported by a contract from the Public Health Agency of Canada.

Introduction

A series of food safety scares and crises in North America and Europe are arguably at the origin of a loss of public confidence in the safety of foods and in government food safety policy-making. Notable recent examples include outbreaks of salmonella or *E. coli* contamination in vegetables and processed meats in the United States and Canada, public debates in Europe about the integration of hormones or genetically modified foods into food production, the spread of Foot and Mouth Disease (FMD) in cattle in the United Kingdom and Canada, and the discovery in 2008 of Listeriosis contaminated cheese in Quebec. These events have left many people with the impression that things "are out of control", raising concerns not only about food safety, but also about government accountability and transparency. Less clear, however, are the reasons for this apparent lack of accountability or the means by which to improve the situation. As we will argue in this paper, it is critical to attend to the social, economic and political dimensions of agriculture (e.g., economies of scale, vertical production integration, international trade, cheap and ready access to quality food products) and the associated diverse and potentially conflicting interests of key stakeholders, most notably food animal veterinarians, farmers/producers, the pharmaceutical industry, and the general public. Only with such an understanding, we suggest, is it possible to comprehend historical and contemporary government responses to

food and public health crises, and be able to positively influence future agricultural and public health policies.

Perhaps the most dramatic case of food contamination was the outbreak, in the 1990s, of Bovine Spongiform Encephalopathy (BSE) or "Mad Cow disease" in sheep and cattle in the United Kingdom. This disease occurs naturally although infrequently in ruminants, and was spread through the common agricultural practice of using bone meal in animal feed, some of which had originated from infected animals; bone meal is an excellent source of supplemental protein, calcium and phosphorous and suitable for use in feeding hogs, chickens and ruminants (1).[1] The great concern about the BSE outbreak was the discovery of a link between this animal disease and the development of variant Creutzfeldt-Jakob Disease (vCJD) in humans, a fatal neurological disease that has proven impossible to treat and exceedingly hard to contain. Over the ensuing decade, recognition of the link between BSE and vCJD lead many countries to change their agricultural practices regarding the composition of animal feed (e.g., prohibitions on the use of bone meal), to introduce more stringent monitoring of food animals (e.g., tracking animals by farm of origin, age, disease-free status), and to initiate restrictive blood donation criteria for public and private blood banks (e.g., in Quebec, people who had lived in the UK or Western European countries considered at high risk for vCJD are prohibited from donating blood (2)).

While the UK and international responses to BSE (and the threat of vCJD) may seem appropriate, studies examining the emergence of BSE in the UK and the actions taken by UK agricultural and health authorities reported serious problems with transparency in the risk assessment process, a lack of communication within and between government departments, and an administrative culture that did not promote accountability (3,4). For example, concern to not destabilize public perception about the safety of the meat production system led officials to de-emphasize possible risk factors for spreading BSE or acquiring vCJD. A decade later, the outbreak of FMD in the UK raised similar issues about public health policy making. Foot and Mouth was an economic disease, and an economic disaster for farmers and communities. Pressure from government to eradicate the disease through the massive slaughter of animals (over six million) was motivated almost entirely by trade and economic considerations, and not the danger posed for human health or that of livestock. The UK Ministry of Agriculture, Fisheries and Food (MAFF) claimed that a mass slaughter was the only way to contain the spread of the disease, despite the ready availability of a vaccine. Vaccination was not considered an acceptable option because of concerns about what the use of a vaccine would imply about Britain's "disease-free" status and its negative impact on international trade (5).[2] The MAFF was influenced by value assumptions about productivity levels, a limited conception of animal welfare, and a presumption that economic interests would be affected if the disease was not eradicated rapidly. There was also a lack of broad stakeholder participation concerning the issue of vaccination (6,7).

In North America and Europe, there has been a growing and largely positive discourse amongst academics and policy makers about the utility and importance of involving various stakeholder groups in health policy making; the idea is that if diverse public voices or

[1] During slaughter and processing, 33-43% of live animal weight is removed and discarded as inedible waste. This includes fat, meat, viscera, bone, blood and feathers that are collected and processed to produce high quality proteins that have traditionally been used to feed animals, including herbivores. However, since the BSE crises, the use of bone meal has been prohibited.

[2] EU regulations prohibit routine preventative vaccination against FMD (and other conditions) in member countries, in order to meet international trade rules for "countries free from foot-and-mouth disease without vaccination" and so avoid trade sanctions or import restrictions on food products.

perspectives are "at the table", then this will lead to better (i.e., more representative, equitable, and publicly acceptable) policy (8-10). However, as has been shown in recent social science research on the use of public or stakeholder participation processes in policy making (e.g., dealing with genetically modified foods, or new biomedical technologies (11-13), one must be wary of seeing these mechanisms as a panacea for problems of accountability and trust. It is essential to recognise the political and economic interests inherent in policy making (e.g., related to food safety and international trade), and consider seriously who would be appropriate stakeholders to involve in any deliberative policy making process.

In this paper, we examine these two issues in more detail through a study of the regulatory system for food animal (and specifically pork) production in Quebec. We focus on moves by professional and government advisory groups to regulate and better manage antimicrobial drug use in pork production in order to mitigate the development of antimicrobial resistance in humans,[3] something that is a widely recognized and growing public health concern. Pork production is one of the leading export sectors of agri-food products in Canada (or was until the recent "porcine" H1N1 flu scare), and Quebec produces the most hogs in the country (1/3 of the total inventory of hogs in Canada (15)); the sector is worth billions of dollars annually to the Quebec and Canadian economies. Unlike other food production sectors, however, pork production in Quebec and the rest of Canada is substantially vertically integrated (described more fully below), so decisions about production practices and the use of antimicrobials are invariably shaped by corporate interests. Yet in contrast to most other jurisdictions in North America where antimicrobials can be purchased over the counter by food producers, in Quebec only veterinarians are permitted to prescribe antimicrobials. But because veterinarians are paid by food producers for their services (and may also generate revenues from prescribing and even selling pharmaceuticals), and are required to protect public health (e.g., by managing/limiting the use of antimicrobials), they encounter challenging conflicts of interest both in their daily practices, and in their participation in the development of public health guidelines and policy. Food animal veterinarians are key actors (and a major stakeholder group) in pork production, the administration of antimicrobial drugs, and in the development of public policy to moderate or limit their use. In this context, we argue that veterinarians' personal and professional interests, and their ethical norms of practice, are key factors to both the problem and the resolution of the current over-reliance on antimicrobials in food production.

Background

Before discussing the ethical challenges related to stakeholder and specifically veterinarian involvement in managing antimicrobial use in Quebec agriculture, it will be helpful to first examine the reasons for the current widespread use of antimicrobials in food animal production, the risks this poses for public health, and the problems it raises for agriculture and public health policy.

Antimicrobial use in agriculture and its public health implications

The development of antimicrobial resistance is a major international public health concern (16-18). Indeed, the growing prevalence of potentially fatal infectious diseases attributed to

[3] According to the US Centers for Disease Control, 'antimicrobials' are a "general term for the drugs, chemicals, or other substances that either kill or slow the growth of microbes. Among the antimicrobial agents in use today are antibacterial drugs (which kill bacteria), antiviral agents (which kill viruses), antifungal agents (which kill fungi), and antiparasitic drugs (which kill parasites)." Similarly, 'antimicrobial resistance' involves "microbes changing in ways that reduce or eliminate the effectiveness of drugs, chemicals, or other agents to cure or prevent infections." (14)

antimicrobial resistant microorganisms raises a very worrisome public health scenario, that is, the large-scale spread of untreatable infectious diseases. Multidrug resistant tuberculosis (1 to 2% of the worldwide cases of TB), methicillin-resistant *Staphylococcus aureus*, and penicillin-resistant and macrolide-resistant *Streptococcus pneumoniae* are all antimicrobial resistant microorganisms that pose serious public health challenges in both developed and developing countries. Antimicrobial resistance is also emerging and spreading among food borne microorganisms such as *Campylobacter* and *Salmonella.* The problem of antimicrobial resistance has been recognized since practically the first use of antibiotic and antiviral drugs in human medicine. Yet it is only in the last few decades that the medical, scientific and public health communities have become aware that antimicrobial resistance now involves almost all genera of microorganisms associated with human and animal diseases.

The cause of this increase in prevalence of resistant microorganisms has been attributed to increasing and often inappropriate use of antimicrobials in human medicine, but also to overuse by the agricultural industries (19-21). The major agricultural use of antimicrobial drugs is in the production of poultry, hogs and cattle, and somewhat less in aquaculture and plants. Antimicrobials are now widely used by veterinarians to treat infections (therapy), to improve growth and feed efficiency (growth promotion), for metaphylaxis (treatment of clinically healthy animals belonging to the same pen or flock, as animals with clinical symptoms) and for prophylaxis (treatment of healthy animals to prevent disease in stress periods).

The use of antimicrobials as growth promoters in food animals such as hogs began in the late 1940s and early 1950s, at a time when food production in North America and Europe was insufficient and too costly to meet growing public demand. During this period, the World Health Organisation (WHO) and Food and Agricultural Organisation (FAO) were set up by the United Nations, with as a priority the development of initiatives to increase global food supply. The 'Green Revolution' in agriculture was seen as a scientific and technological revolution: technical, biological and mechanical innovations — alongside substantial financial capital investments through agricultural subsidies — would enable industrialized and developing countries to both meet their growing national food needs and to participate in the expanding global agricultural market (22). One such technical/biological solution was the widespread use of low concentrations of antimicrobials to stimulate food animal growth and increase the yield of meat per unit of animal feed (23). Low concentrations of antimicrobials moderately inhibit the growth of microbial flora, especially the lactic flora. This results in a preservation of carbohydrates and proteins in the small intestine, decreased transit across the large intestine and bowel, an increased production of volatile fatty acids, and thus increased availability of nutrients and energy for animal growth (24).

To put this issue into perspective, the amount of active ingredient consumed per hog after weaning (on average four months) is 37g in Québec, 40g in France, but only 3g in Denmark (25). These differences reflect to some extent variation in the scale of industry but arguably have more to do with scientific and policy choices about the appropriate use of antimicrobials. Given the massive scale of contemporary agricultural production in North America and Europe (e.g., the Canadian inventory of all hogs in 2006 was 15 million animals; in the US, the inventory was 61 million animals) (15), very large quantities of antimicrobials are being used. Of note, 50% of all antimicrobials sold around the world are now used in food animal production (21). Most of these drugs are the same or very close in chemical structure to the antimicrobials used in human medicine, providing favourable conditions for selection, spread and persistence of antimicrobial resistant pathogenic and commensal

bacteria[4] in animals. The problem for human health is that these resistant bacteria or the resistant genetic determinants (particularly when they are multi-drug resistant) may be transmitted to humans via the food chain or by direct contact with animals (26-28).

By the 1960s, it was already quite well recognised in the agricultural and scientific communities that the prolonged use of antimicrobials favoured the appearance of resistant microorganisms. For example, in 1969 the UK's Swann Committee recommended restricting the low-level use of therapeutic antimicrobials (i.e., antimicrobials used to treat human diseases) in animal feed (29). Yet despite this recognition of the public health problems posed by antimicrobial use in food production, North American and European regulatory authorities continued to accept if not actively encourage the use of antimicrobials (e.g., in feed additives) as growth promoters and prophylactic drugs for food producing animals (30). Consumers in North America and Europe had come to accept — and even demand — that food would be safe and affordable. The commercial and economic implications of the new antimicrobials as management tools (e.g., reduction in disease outbreaks, increase in food yield) were simply too attractive, and arguably one of the reasons for a general lack of concern about the development of antimicrobial resistance in food producing animals.

This failure to question the implications of widespread and often indiscriminate use of antimicrobials was further supported by the traditional strategy of the pharmaceutical industry to deal with antimicrobial resistance in the context of human health care. That is, every time resistance appeared against a particular antimicrobial drug, a new antimicrobial or class of antimicrobials would be developed and introduced into human and veterinary medicine, and into animal food production management. Unfortunately, while the first 30 years following the discovery of penicillin saw the introduction of a multitude of antimicrobials that were able to stay ahead of resistance, during the last 25 to 30 years only one new family of antimicrobials (the oxazolidinones) has been introduced. It seems that this market has lost its appeal to "Big Pharma" (31,32), arguably because the classical response of developing a new antimicrobial or class of antimicrobials every time resistance appears has become untenable (33,34). There is now general scientific agreement that the only viable option to limit resistance development is to decrease the selection pressure on resistant microorganisms, which entails decreasing antimicrobial use. Yet as already mentioned, modern food animal production has become dependent on the use of large quantities of antimicrobial drugs, a linkage that is no longer sustainable.

Policy strategies to reduce antimicrobial resistance

In recent years, international guidelines concerning the use of antimicrobial drugs in food-producing animals have been developed, including for example, the *WHO Global Principles for the Containment of Antimicrobial Resistance in Animals intended for Foods* and the *OIE Guidelines on Responsible and Prudent Antimicrobial Use* (19,35). These guidelines provide a framework of actions to take to reduce the overuse or misuse of antimicrobials in order to protect human health. They include recommendations on pre-approval, manufacturing, distribution, sales and the prudent use of drugs. They also promote resistance surveillance programs, and education of veterinarians and farmers (food producers) about the appropriate use of and dangers associated with misusing antimicrobials in food animals. Some of these policies have even gone so far as to recommend a complete ban on the use of antimicrobials as growth promoters in the absence of detailed risk assessments, if these drugs are also used in human therapy. Concerns about the need to respond to the growing public

[4] That is, bacteria that live in a symbiotic relationship with the organism.

health challenge of antimicrobial resistance have also stimulated international professional and scientific conferences, including a number in Canada, and led to the development of policies and guidelines at both the national and regional levels. Unfortunately, both in Canada and internationally, there seems to be great difficulty in translating these directives into concrete, practical recommendations that acknowledge the range of interests involved, and so be acceptable to the key stakeholders such as farmers, veterinarians, and food production companies.

In October 2005, the Ontario Ministry of Agriculture Food and Rural Affairs, and the Public Health Agency of Canada, organised a conference entitled *Agriculture's role in managing antimicrobial resistance — The road to prudent use,* which was a follow-up to a similar conference held in 1999. The conference brought together many stakeholders, including research scientists, members of regulatory agencies, representatives from the pharmaceutical and food industries, members of the medical community, and food animal veterinarians. The aim was to discuss the changes in antimicrobial resistance since 1999 and to determine how to improve antimicrobial use in agriculture in Canada over the next five years. The outcomes of this meeting included a series of recommendations to guide antimicrobial use: 1) the need for clinical practice guidelines on prudent antimicrobial use; 2) mandatory enrolment in On-farm Food Safety (OFFS) programs;[5] 3) the production and availability of national surveillance data; 4) improved education of veterinarians and food producers about antimicrobial usage and antimicrobial resistance; and 5) improved scientific knowledge. While these recommendations are certainly a positive step, they are somewhat bureaucratic in nature (a focus on quality control and participation in screening programs) and are often distant from the practical realities of the food animal veterinarians or food producers using antimicrobials. For example, while the collection of national-level data about antimicrobial use and resistance is helpful when the spread of an animal pathogen has been recognized, these data are not directly useful for the practicing veterinarian who needs information about a specific farm or production system (e.g., relative disease status, relative ages of animals, purpose of use of antimicrobials) (36).

An examination of reports prepared in 2002 and 2005 by Health Canada's Advisory Committee on Antimicrobials in Food Animals in Canada finds similar general statements with relatively few specifics or practical recommendations for the key stakeholders (37,38). These reports also seem to be premised on the notion that the problems posed by antimicrobial use in food animals can be resolved primarily through the application of rigorous scientific research and a quantification of the relevant risks and benefits. That is, problems will be solved through "a risk-based decision-making approach embracing management strategies that are appropriate or proportional to the expected risks from the use of a product". (38) Yet there is little in the way of specification about how to arrive at the ultimate decision to use or not to use antimicrobials; veterinarians are encouraged to be "responsible and judicious" and to act according to the Canadian Veterinary Medical Association "prudent use" principles. These principles state that veterinarians should assist clients with the design of proper programs to reduce disease and antimicrobial usage; consider alternative therapeutic options, dispense and prescribe antimicrobials only within the confines of a valid veterinarian-client-patient relationship; and properly select and use

[5] The motivation to develop these OFFS programs is linked to efforts to maintain the international competitiveness of Canadian agriculture. These programs are based on Hazard Analysis Critical Control Point (HACCP), an internationally accepted food safety assurance system. The Canadian Pork Quality Assurance (CQA) program is the producer component. Elements of the program include producers' operating manuals and the requirement for careful record keeping, traceability programs and auditing of the program on farms. The program is based on critical control points of good production practices, including medical supplies (use and storage).

antimicrobial drugs (39). Finally, there is no attention to the practical challenges facing veterinarians or food producers, and in particular, the social and economic pressures that promote the very excesses in antimicrobial use that these policies seek to reduce.

In Quebec, the Ministère de l'Agriculture, Pêcheries et Alimentation du Québec (MAPAQ) is working towards a ban on the use of antimicrobials as growth promoters in hogs. To justify this eventual ban, MAPAQ commissioned a study on the use of antimicrobials in growing-finishing hogs, to be conducted by ÉpidémioQualité Inc. (final report, December 2007) (25); in parallel, MAPAQ's Sous-groupe de travail sur l'antibiorésistance conducted a study on the social impact of such a ban, entitled *Evaluation de l'impact de l'interdiction de l'utilisation des antibiotiques comme facteurs de croissance*. (It should be noted that the use of antimicrobials as growth promoters is banned in the European Union, and there have already been several studies on this subject (40,41)). While the MAPAQ studies might lead one to conclude that the Quebec government is taking into account the social and economic implications of such a prohibition and is not simply focusing on the technical or scientific considerations, the actual practice of policy development seems to reflect the more traditional technocratic approach of their provincial (e.g., Ontario) and federal counterparts. For example, the MAPAQ studies were conducted with limited transparency or public accountability. Of particular note is the fact that the list of the working-group members (which included veterinarians), and the report and recommendations of the Sous-groupe de travail sur l'antibiorésistance which were finalized in December 2006, only became available in September 2008; the reason for this delay is unknown.

In Quebec, and in Canada more generally, the subject of antimicrobial resistance in agriculture is "super sensitive". When the issue is raised with provincial and federal policy makers, one senses an unease and a reticence to discuss the issue in detail. Policy makers hide behind claims about a "need for confidentiality" and assertions that "work is ongoing but not yet ready for public dissemination" (42). Specific enquiries by interested parties into the actual policy development process — or more general queries about what should be the appropriate response to preventing antimicrobial resistance — are arguably perceived as a threat by those involved. The sensitivity of this subject for the various stakeholders shows clearly that the challenges are more than simply technical; there are fundamental social and economic interests at play. Veterinarians, food producers, researchers, or those appointed to committees and workgroups, face the difficult and so far unanswered question: how can the Canadian agricultural sector — which is worth billions of dollars to the economy and employs tens of thousands of people — move beyond its dependence on antimicrobials?

The problem with existing policy approaches (whether provincial or federal) to addressing the public health challenge posed by antimicrobial resistance is that they involve a very narrow conceptualization of the relationship between antimicrobial use and society; as such, they ignore the broader and potentially conflicting social, economic and political interests of the various stakeholders. Policies have a tendency to be formulated by agricultural and public health agencies, with limited or even biased stakeholder consultations, as if the response to the problem of antimicrobial use in agriculture can be purely technical. Following the release of the report and recommendations of the Sous-groupe de travail sur l'antibiorésistance, in September 2008 the MAPAQ created a new working group, the Groupe de travail sur la prévention de l'antibiorésistance et l'utilisation judicieuse des antibiotiques, whose mandate is to establish priorities and develop an action plan that implements the Sous-groupe's initial recommendations. But once again, the priorities and recommendations of the new working group are essentially technocratic in nature, involving for example, the implementation of

surveillance systems of antimicrobial usage and resistance development, or technical recommendations concerning “judicious or rational” usage of antimicrobials to be disseminated through veterinary education, guidelines for veterinarian use of antimicrobials, research, etc. There is little or no attention given to the social or economic realities faced by the veterinarians, food producers and food production companies who must implement these recommendations. (The composition of the working groups will be discussed in the following section).

Our contention, and one that is substantiated by decades of research in the field of Science and Technology Studies (STS), is that technologies necessarily incorporate particular social or moral values, and are socially and culturally embedded (43). While it is clear that diminishing antimicrobial use in animal food production is an important public health goal that requires rational political decisions based on sound scientific data, risk assessment studies and other technical information, these decisions cannot be justified simply on scientific grounds or through technocratic processes. For a policy response to be effective, and more importantly for it to be acceptable and ultimately accountable to the diversity of stakeholders, it must move beyond a narrow technocratic response. That is, policy makers should — whether through their own analyses, or through more direct stakeholder consultations — pay particular attention to the social, economic and moral values at stake, and the diverse and potentially conflicting interests of the range of stakeholders involved in the use of antimicrobials in agriculture. This is particularly important in the context of antimicrobial usage in hog and other food animal production, because any significant modification of current usage will imply major modifications to farm level management procedures, and ultimately even necessitate a complete re-thinking of modern animal production practices.

The Social Context of Veterinarian Practice

Antimicrobials are an essential means by which small family farms in North America and Europe evolved, in the 1950s and 1960s, into intensive, business-oriented food animal production facilities. Pork production followed a similar pattern of scaling-up, but then in the 1990s saw an exceptional intensification that is arguably a separate socioeconomic phenomenon from scaling up. In Quebec, almost 50% of pork production is done by independent producers, and 50% by producers working under contract from integrated agribusinesses (44).

The independent producer in general possesses the full range of goods necessary for the operation (including land, buildings, equipment and animals), and supplies are purchased from a variety of wholesalers. The contract producer owns land, buildings and equipment, but not the animals, which are supplied by the integrated agribusiness who are the owners of the animals and pay the producer for delivering grown animals for slaughter; the contract producer may also receive bonuses depending on levels of mortality and other quality measures. The integrated businesses combine within their operations many if not most of the elements involved in pork production, transformation and distribution — i.e., they own the piglets, equipment, feed, antimicrobials, finished hogs, processing and packaging — and so these companies are said to be “vertically integrated”. The marketing of hogs is also increasingly structured through collective pricing agreements to stabilise prices over the long term and also ensure that producers receive the same price per animal produced (e.g., in Quebec, pricing is fixed by the Assurance stabilisation des revenus agricoles de la Financière Agricole, ASRA). Given that the amount of income generated per pig is outside the control of producers, the only way to increase revenue is to reduce the costs of production.

These modern food production conditions are now dependant of antimicrobial use. Food animal production is a complex biological process linked to a complex management skill. It is no longer “farmers” who raise animals, but instead “food producers” who optimize the growth and production potential of food animals through the management of living environments, selection and modification of feed, selective scientific breeding for trait selection, etc. Production settings range from the relatively small family farm with hundreds of animals to large-scale operations with thousands or tens of thousands of animals. Important differences also exist between farms with regards to the animal species being raised, their geographical location, market conditions, production sizes, management methods, and the possibility of treating individual animals versus group treatment.

The optimization of growth and production also requires the optimization of the health of both individual animals as well as the herd or flock. Depending on whether a farm or “production facility” is confined (e.g., larger battery chicken facilities or hog farms that employ various levels of biosecurity) or non-confined facilities (e.g., “free-range” chickens or beef cattle ranches), they may use considerable or limited amounts of antimicrobial drugs. In large, confined operations, there is a greater risk of disease spread across a population and thus a concomitant need for wide scale prophylactic treatment; free-range animals may also need prophylaxis given greater environmental exposure to microbes. However, as mentioned previously, with the exception of some organic food animal production, antimicrobials are also widely used for growth promotion across animal species (although at much lower concentrations), both in confined and non-confined operations. Food producers are thus major consumers of antimicrobial drugs, and it is veterinarians who prescribe them.

Professional Responsibilities

Food animal veterinarians take a professional oath to promote and protect animal health and welfare, relieve animal suffering and protect public health regardless of the agricultural production setting. The Canadian Veterinary Medical Association (CVMA) is committed to excellence within the profession and to the well-being of animals, and while the Association does not have a specific code of ethics it does have position statements on animal welfare (45). The code of ethics of veterinarians in Quebec (Ordre des médecins vétérinaires du Québec, OMVQ) includes duties to the public, clients, the profession and animals (46). The code focuses mainly on professional conduct in relation to clients and colleagues, with the interest of animals and public health being considered as implicit rather than being discussed explicitly.

The CVMA identifies antimicrobial residue prevention as a national issue that is “addressed by the CVMA on behalf of the profession”. (47) Guidelines on the Prudent Use of Antimicrobial Drugs in Swine have been approved by the CVMA; they concern antimicrobial usage for therapeutic treatment, control and prevention of bacterial disease. The CVMA guidelines specify that veterinarians should dispense and prescribe antimicrobials only within the confines of a valid veterinarian-client-patient relationship and that they should, for example in the case of pork production, use the Canadian Quality Assurance (CQA) program (48) of the Canadian Pork Council as a basis for the judicious use of antimicrobials (39). As already mentioned, in Quebec, antimicrobials (including antimicrobial drugs used as growth promoters) are available only with a veterinary prescription and supervision, and are distributed exclusively by veterinarians and pharmacists. In the other Canadian provinces and in the US, antimicrobials are sold freely over the counter, and feed manufacturers prepare and sell medicated food to producers. This medicated food is used for treatment and prevention of specific diseases as well as for growth

promotion. In Quebec, feed manufacturers must receive an appropriate veterinarian prescription from food producers, prior to selling their medicated animal feeds.

Conflicts of Role and Interest

In the use and regulation of antimicrobials, food animal veterinarians are a key actor. This profession bridges and helps negotiate relations between the other stakeholders involved; that is, veterinarians stand between food producers (and animals) who are the end users of antimicrobials, the pharmaceutical industry which produces and sells these drugs, and agricultural and public health regulators seeking to control the use and limit the negative impact of antimicrobials (See Figure 1).

Portrait of Antimicrobial Distribution in Quebec

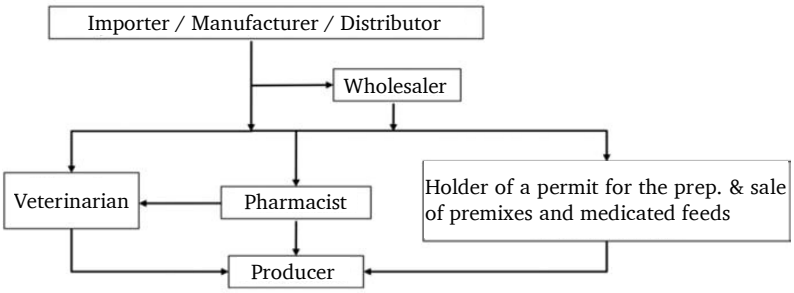

Figure 1. Adapted from Annex 1 of the report by the Sous-groupe de travail sur l'antibiorésistance / Groupe qualité. April 2006. *Distribution des antimicrobiens au Québec : Sources de collecte des données en continu*, Québec : MAPAQ, p. 24.

As already noted in the previous section, veterinarians have different responsibilities towards and relations with each of these stakeholders or interested parties. Veterinarians have the professional responsibility to limit their prescription of antimicrobials for public health reasons; in the various policy statements already discussed, vets are charged to prescribe only those drugs that are appropriate for managing the disease in question. Yet their clients, food producers, need antimicrobials for management use, and in Quebec, usually purchase these drugs directly from veterinarians, who in turn purchase them from the pharmaceutical industry or drug wholesalers; in other Canadian provinces, food producers may purchase antimicrobials directly from the pharmaceutical industry.

Being at the same time prescriber and vendor places food animal veterinarians in a difficult conflict of interest; they may and often do obtain a significant portion of their income from the sale of the antimicrobials they prescribe, and thus may have a strong financial interest in selling drugs that are contrary to other, e.g., public health, interests. This conflict, which is identical in the case of human health, has in many jurisdictions resulted in prohibitions or restrictions on physician referral practices; to avoid the financial conflict of interest, physicians may be prohibited from prescribing medications or referring for services provided by clinics in which they are owners or partners (49,50). At the same time, physicians — and by analogy, veterinarians — play an important role in managing the use of costly and potentially dangerous medications, thus the importance of requiring prescriptions for many medications (and not permitting over-the-counter sale). It is interesting, then, to question why such conflicts are still permitted by current Canadian agricultural regulations — and why prescriptions are not required in provinces other than Quebec — when such actions may undermine the safety of food production and threaten public health.

To further complicate matters for veterinarians, they face two other types of conflict between their professional obligations and their practical responsibilities, i.e., in their relationship

with food producers and in the appropriate selection of antimicrobials. The aforementioned CVMA Guidelines on the Prudent Use of Antimicrobial Drugs in Swine require vets to prescribe antimicrobial drugs only within the confines of a valid veterinarian-client patient relationship. Yet food animal production in Canada and internationally has evolved into large scale agribusiness, so the relationship between veterinarians and food producer has changed. The farmer/owner of animals is increasingly being replaced by the producer/owner of animals as economic units, and this has a direct impact on veterinary prescribing practices and the management of antimicrobial use. That is, veterinarians are asked to both prevent/treat animal illness and to support the growth promotion of animals, health and economic outcomes made possible by the use of antimicrobials; but then veterinarians are also asked to manage (and even limit) the use of antimicrobials in the name of public health.

In this context, veterinarians face important challenges in working with independent and contract producers, and also with vertically integrated agribusinesses. Vets are asked, even pressured, to prescribe antimicrobial drugs both for medical reasons (treatment, prophylaxis) and for growth promotion (use in food additives); and they have both professional and financial incentives to accommodate these requests. Yet their professional codes, and the recommendations of national and international guidelines, run counter to these demands. Vets are encouraged to properly select and use antimicrobial drugs, but due to the production methodology involved in contemporary agribusiness — i.e., large numbers of animals in the same pen, and several pens in the same building — in many cases individual animal treatment is almost impossible, and not only for curative treatment but also for prevention and for metaphylaxis. As a result, veterinarians have no other choice than to prescribe large amounts of antimicrobial drugs, both for treatment and growth promotion.

These professional conflicts of interest and responsibility highlight the extent to which the prescription of antimicrobials is never a purely medical decision. Instead, prescription also invariably involves judgements that are influenced by a veterinarian's professional responsibilities to their patients (animals), their clients (food producers and food production companies), and to the general public (public health considerations). Some of these decisions may involve conflicts of interest, others may not; some of the conflicts may be avoidable or manageable, while others may be sufficiently serious that formal regulation or changes to practice and policy will be required. The point is that these various veterinarian interests, and their interrelation with the interests of producers and agribusinesses, are directly associated with the management of antimicrobial resistance.

Role in Policy Making

As the primary prescribers of antimicrobials, food animal veterinarians can and should play a more important role in the creation of policies to control antimicrobial resistance. But veterinarians have the distinct impression that their concerns and interests are not taken into account in policy studies and eventual decision making.[6] As already discussed, in Quebec the MAPAQ created two working groups to address the issue of antibiotic resistance, and while these groups did include veterinarians as members, the resulting studies and reports have tended to be technocratic in nature. We suggest that this situation can in part be explained by the composition of these working groups, and specifically the issue of representation of *practicing* food animal veterinarians.

[6] Observation made by Doizé at the Association des Vétérinaires en Industrie Animale (AVIA) meetings and reply of the AVIA to the MAPAQ Sous-groupe de travail sur l'antibiorésistance recommendations.

When the Sous-groupe de travail sur l'antibiorésistance submitted its report to the members of Association des vétérinaires en industrie animale (AVIA) in 2006, this produced a very strong reaction, not only against the contents of the report (which was perceived to have ignored practices already in place in the veterinary profession), but also because of a lack of effective representation on the part of AVIA during the consultations about antimicrobial resistance (51). While 7 veterinarians were members of this working group, they were for the most part scientists (e.g., epidemiologists, pathologists or microbiologists) and not practicing veterinarians. These veterinarians were from the Association québécoise des industries de nutrition animale et céréalière du Canada (n=1), the Public Health Agency of Canada (n=1), and the MAPAQ (n=3); there was only one member representing the AVIA and one from the Ordre des médecins vétérinaires du Québec (OMVQ). Interestingly, the membership of the Groupe de travail sur la prévention de l'antibiorésistance et l'utilisation judicieuse des antibiotiques (created in 2008), seems to be more politically correct; it now includes representatives from the full range of veterinarian stakeholders, that is, the OMVQ, AVIA, Académie des médecins vétérinaires du Québec, the Faculté de médecine vétérinaire at the Université de Montréal, MAPAQ, and the Public Health Agency of Canada. But will this broader representation of scientific and practicing veterinarians lead to more practical and politically acceptable recommendations, and importantly, will it address the important conflicts of interest at stake for veterinarians and other stakeholders?

There is a sense among many practicing veterinarians that the MAPAQ working groups are "re-inventing the wheel" while also restricting veterinary practice (e.g., requiring more detailed prescriptions, which while appropriate, is perceived as a further imposition). The recommendations of these working groups reflect the experiences and professional judgments of their members, which is not surprising; such is the nature of any working group. But in focusing on a review of the scientific literature, technical analyses, and quantitative studies of the use of antimicrobials, the impact of the working groups' recommendations on the daily practice of veterinarians have and continue to be ignored. It is important to also recognise that such techno-scientific approaches to dealing with the issue of antimicrobial resistance are widespread. Even the AVIA, for example, has argued that the number one priority is for Health Canada to conduct risk analyses related to the impact on human health of the use of antimicrobials in animals. AVIA is silent regarding concerns about the economic aspects of the use of antimicrobials (especially the financial pressures for food producers and food production companies), the conflicts of interest and responsibility facing veterinarians, or the need to more fully re-think current food animal management practices. So while the recommendations of the working groups arguably reflect a political willingness (from government and professional associations) to reduce the use of antimicrobials — and there are some useful recommendations regarding improved monitoring and data collection — there has not been a concomitant willingness to seriously question the current practice of industrial food animal production in Canada.

Conclusion

There is international, national and provincial consensus that, for public health reasons, the current practice of antimicrobial drug use in food animal production needs to be changed in order to reduce their misuse and overuse, and mitigate the important public health risks associated with antimicrobial resistance. For many years now, Canadian and Quebec public health and agricultural authorities have been working on this problem. Unfortunately, the guidelines put forward consist essentially of technocratic recommendations (such as surveillance programs, risk assessment studies), suffer from a lack of timeliness and transparency, and pay little attention to the underlying social and economic realities (and

interests) of the various stakeholders involved, and in particular we argue, those of food animal veterinarians.

The issues associated with antimicrobial use in food animal production are complex. Agriculture in Canada is intensive, specialised, industrial (often vertically integrated), a major part of provincial and national economies, and operating in an international and highly competitive market. In the context of food animal production, antimicrobial drugs have become an essential management tool. The social and economic interests at stake are huge — for the agricultural sector, food producers and veterinarians, but also for consumers and politicians. For example, imagine that Canadian health and agricultural policy makers decided to prohibit the use of antimicrobials for growth promotion in food animals in the name of public health, as is the current practice in Europe. The negative consequences might well include increased production costs and thus more costly food, decreased competitiveness in relation to the American and Asian agricultural sectors, farm failures and a demand for subsidies and bailouts, and finally an off-shoring of agribusinesses. Even just one of these potential consequences would be a political "hot potato". So it should not be surprising, then, that discussions about reducing or changing current practices provoke a high level of sensitivity, an obscuring of the positions of those involved in the policy making process, and create dissatisfaction on the part of many of those stakeholders most affected, namely veterinarians, food producers and food production companies. Any moves to make significant changes to antimicrobial use will likely require a complete rethinking of food animal production practices, something that seems unlikely in the current economic and political climate. Yet as we have shown, the public health reasons for reducing agriculture's reliance on antimicrobials are important. Where, then, is there any room for hope?

In Quebec, it is veterinarians who have the power to prescribe antimicrobials, and as such, they are important gatekeepers in regulating access to antimicrobial drugs; other provinces would be well advised to follow this lead in order to control access to and use of antimicrobials in food animal production. Yet critical attention must also be paid to the professional and economic interests at stake for food animal veterinarians, and the potential and real conflicts of interest that arise when vets prescribe antimicrobials. Lessons can and should be learned from moves to manage the conflicts of interest facing physicians (e.g., separating payment for treatment and prescription), so that they — and veterinarians — can meet their professional and ethical responsibilities towards their clients and patients. Broader public health policy to limit the use of antimicrobials in growth promotion is essential, but re-thinking the current reliance on antimicrobials remains a major challenge due to the important economic and political interests at stake. Developing such policy, we have argued, entails moving beyond the traditional reliance on techno-scientific analyses of antimicrobial risk and benefit, to more fully integrated reflection on the range of stakeholder interests and values at stake in contemporary agriculture.

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Identification and management of conflicts of interest: governance tools for the Observatory on the Quality of the Food Supply

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Original version: Williams-Jones B, Cloutier A-I, Roy M-C. Identification et gestion des conflits d'intérêts : document de travail en appui à l'analyse du comité aviseur en éthique. Report submitted to the Ethics Adivsory Comittee of the Observatoire de la qualité de l'offre alimentaire, INAF, Université Laval. 13 Nov 2017.

Contributorship

BWJ, AIC and MCR drew up the work plan. AIC and MCR carried out the literature review with the support of BWJ. AIC and MCR each wrote part of the text. This underwent several rounds of revision by the three team members, after which AIC and MCR made corrections. Then, a complete draft — a working document — was submitted for comments on December 2017 to the Ethics Advisory Committee of the *Food Quality Observatory* (Institute on Nutrition and Functional Foods, Université Laval); we acknowledge the detailed and constructive criticism of Lyne Letourneau and Laurelie Trudel. The final document presented here has been revised and approved by all three authors.

Financing

The research and production of this document were funded by a generous grant from the *Food Quality Observatory*.

Introduction

Diet is a fundamental public health issue. In Quebec, cardiovascular disease, for which diet has been shown to have a definite aetiological impact (1), causes 24.5% of deaths and is the second leading cause of death after cancer in the province (2). In this context, research into nutrition, which generally aims to gain a better understanding of how it influences health, is crucial.

Economic, political and academic factors often make it necessary to establish collaborations between the nutrition research community and the agri-food industry. In some cases, these partnerships can be vital — and therefore indispensable — to the smooth running of research laboratories. However, the agri-food industry — multi-billionaire and international — is often criticized for being more concerned with profits than with people's health. The respective missions and objectives of nutrition research (scientific objectivity, protection and improvement of public health) and the agri-food industry (maximisation of profits) can appear to be in conflict, calling into question the legitimacy and credibility of collaboration between these two players.

Because of the possible tensions between the respective interests of nutritional research and the agri-food industry, there is a risk of conflicts of interest (COI). The presence of COI in research and other professional circles is often unavoidable, as it is inherent in individuals to have interests beyond their professional duties (3). It does not necessarily mean that an individual (or an organisation) is ill-intentioned or lacks integrity. It is therefore important to rid oneself, without losing one's critical mind, of negative prejudices towards all COI (4). Nevertheless, while COI are sometimes unavoidable, it is essential to manage them ethically.

The aim is to reduce the associated risks as much as possible, i.e., the risks of bias, erosion of public confidence and erosion of the confidence of stakeholders. Since trust is a guarantee of an organisation's social usefulness and its ability to engage key players, good management of the links of interest between a research institution and its members can help to consolidate these attributes.

The Food Quality Observatory (*Observatoire de la qualité de l'offre alimentaire*; hereinafter "the Observatory") was inaugurated in 2016 at Université Laval's Institute on Nutrition and Functional Foods (*Institut sur la nutrition et les aliments fonctionnels*; INAF). Its mission is to "[o]bserve and monitor changes in the food supply in order to generate new knowledge and act collectively to improve its quality and accessibility." (5) It is also intended to be a neutral platform for "establishing concrete dialogue and concerted efforts between the agri-food and public health sectors" (5). Like any academic research organisation, the Observatory (and its members) is subject to various factors that could place it in a COI situation, particularly if it intends to facilitate collaboration between the private and scientific sectors. With a view to observing the values of rigour, transparency, objectivity, commitment and social usefulness in its decisions and actions (6), the Observatory has put in place various mechanisms to ensure the ethical management and operation of the organisation, particularly with regard to COI. These mechanisms include the mobilisation of an Ethics Advisory Committee (EAC) and the articulation of the five values mentioned above. The drafting of this chapter — which presents the results of a process of reflection on the sound management of COI — is therefore in line with the Observatory's desire to equip itself with an ethical governance framework that is congruent with these values, as well as with those of the INAF, where ethics and scientific rigour are fundamental values (7).

The development of a policy for managing links of interest adapted to the Observatory's situation is essential for several reasons. Firstly, in view of its desire to become a recognised benchmark at the Canadian and international level on issues relating to the quality of the food supply, the Observatory must protect its integrity, independence and credibility, which are guaranteed by good management of links of interest. If it achieves the desired reputation, the Observatory will become a key player that companies may seek to influence through various strategies, thereby increasing the risk of COI.

Secondly, in order to achieve their objectives of improving the health of the population, the provincial and federal governments are encouraging organisations working in the food sector, including the Observatory[1] , to take action in the fight against obesity. At the same time, these governments are encouraging all sectors that can play a role in this fight (private, public, semi-public, academic, non-profit organisations) to form multi-sector collaborations.[2] Thus, if the Observatory wishes to play a central role in improving the food supply, as well as the public health mission of reducing obesity, its interests will undoubtedly be opposed, to one degree or another, to those of potential private collaborators from the agri-food industry.

[1] In Quebec, the document Vision de la saine alimentation specifically invites "actors in the food supply to become more aware of their role in improving Quebec's food landscape".
[2] For example, in Canada, the 2016-2019 Strategic Plan Improving Health Outcomes — A Paradigm Shift stresses that "we need to focus more on mobilizing resources and skills from other sectors, such as the public, not-for-profit and corporate sectors".

With this in mind, this chapter aims to:

1. summarise the literature on COI in nutrition research and on good institutional governance of collaborations between the agri-food industry and nutrition research;
2. explain the analysis that underpinned the deliberations of the Observatory's Ethics Advisory Committee (EAC) on the management of links of interest and COI situations;
3. to present recommendations for the ethical management of links of interest between the Observatory and its members, as well as possible collaborations with industry.

With its origin as a working document, this chapter responds specifically to issues relevant to the Observatory. Nevertheless, the analysis presented here as well as the recommendations and tools are generalisable to other academic research environments.

Review of literature

This first part aims to summarise the literature on the subject of COI (definition, causes and consequences) in nutritional research. It is divided into 7 sections:

1. Short description of COI and the biases they can cause in research.
2. Presentation of the similarities between nutritional and pharmaceutical research, and between the agri-food and pharmaceutical industries. This will make it possible to compare research-industry collaborations in these two fields, and possibly to extrapolate the literature on collaborations in pharmaceutical research (which is more complete) to nutritional research.
3. Presentation of the factors that can increase the risk of COI in nutritional research, i.e., the lack of public subsidies, the type and interests of the financial partner, the intensity of the link of interest, and personal interests.
4. Distinction between COI caused by personal interests and ideological bias.
5. Discussion of the loss of public and stakeholder confidence that can result from COI.
6. Discussion of the benefits of collaboration between nutritional research and the agri-food industry.
7. Short summary.

Understanding conflicts of interest in research

According to the terminology used by the Haute Autorité de Santé, in France, COI emerge from a link of interest, i.e., a commercial, financial or non-financial relationship, between two or more entities. A link of interest may be *real*, i.e., actually existing (8); *potential*, i.e., not currently existing, but likely to materialise (8); or *apparent*, i.e., not actually existing, but appearing real to a third party (9). Depending on their intensity, which depends on various criteria such as the amount of money involved, seniority, duration, frequency, etc. (10), real, potential or apparent links of interest may give rise to real, potential or apparent COI. In other words, measuring the intensity of a relationship of interest makes it possible to assess whether a COI exists (11).

Thus, the absence of a link of interest means the absence of COI (10). A minor link of interest poses a low risk of COI (12), as it appears at first sight to be reconcilable with the exercise of the function or the completion of the mandates of the collaborating entities. It therefore gives rise to a presumption that there is no COI (11). Conversely, a major link of interest

poses a high risk of COI (12) since it gives rise to reasonable doubt as to the declarant's impartiality in the performance of his duties or the completion of his mandate. It therefore gives rise to a presumption of COI and requires a certain amount of attention (11).

A COI, which arises from an objectively observable factual situation (i.e., the presence or absence of links of interest), runs the risk of subjecting an individual's professional judgement regarding the duties and responsibilities associated with his or her position or status to the undue influence of a secondary interest. Thus, a COI is a *possible* source of bias (13), i.e., a prejudice in favour of or against something (14). Note that bias can also be caused by factors other than COI, such as ideological and identity factors (culture, gender, socio-economic conditions, etc.).

Furthermore, when institutions with different or opposing primary interests collaborate, there is a risk of institutional corruption, particularly if the major links of interest arising from the collaboration are poorly managed. Institutional corruption involves the perversion of the mission of one of the two institutions (e.g., incorporating interests of the other institution that are not compatible with its mission) (8). It can also be observed when, in the presence of influence strategies (considered legal or ethical), an institution struggles to pursue its mission, thereby eroding the quality of its internal structure and the public's confidence in it (15). In contrast, institutional integrity is the consistency between the effects of an institution's day-to-day actions/initiatives and the missions, values and objectives it claims to pursue (8). An institution with integrity is usually characterised by the ethics of its institutional culture.

The COI that arise during collaboration between the academic (or public) sector and the private sector (e.g., the agri-food industry) are very often financial in nature. A COI can cause bias, i.e., a favourable or unfavourable prejudice, and thus affect professional judgement. In the academic world, an COI caused by collaboration with a partner whose interests diverge from those of the research may result in studies biased in favour of the financial partner, e.g., in pharmaceutical research (16,17) and nutritional research (18-20). In addition, studies with negative conclusions funded by industry are less likely to be published than those funded by governments, resulting in another type of bias, namely a bias in the publication of results (21).

As far as nutritional research is concerned, its funding by the agri-food industry poses four problems which accentuate the risk of systematic bias in favour of the private funder. These problems are well summarised by Simic (8), taking up Marks' proposal:

> Firstly, the [agri-]food industry is primarily interested in research that enables it to promote or defend its products (Marks, 2014). Secondly, by targeting the problems and research questions that are funded, it influences the topics that are the subject of scientific research (Marks, 2014). Third, it shapes how research questions are asked, and generally focuses on the positive aspects of its products, rather than exploring the negative aspects or harmful elements that might be attributed to them (Marks, 2014). Fourthly, in the majority of cases, the [bio]food industry proposes technological and individual solutions to social problems, since this type of solution has the advantage of being marketable, and therefore brings it profits (Marks, 2014).

For all these reasons, research funded by the private sector may be biased in its favour (i.e., its economic interests) rather than in favour of the public health objectives associated with nutritional research.

Similarities and differences: COI in nutritional and pharmaceutical research

Research into COI in the field of nutrition is fairly recent compared with that into COI in pharmaceutical research, but it is gaining in importance (22,23). Today, the expression "Big Food" echoes that of "Big Pharma", pejorative terms referring respectively to the agri-food and pharmaceutical industries and their significant (bad) political influence. These industries can influence governments directly via lobbies but given that the development of public health policies is based on evidence, they can also influence them indirectly via scientific studies, which can be used to make decisions. As we have seen, studies funded by the private sector can be biased in its favour.

There are similarities between the pharmaceutical and nutritional/food sectors which make it possible to extrapolate COI risks from the former to the latter. Even, as described in the following paragraphs, the agri-food industry sometimes uses strategies similar to those used by pharmaceutical companies to bias research in its favour. However, it is understood that an in-depth analysis remains to be carried out to document and support this hypothesis in a strictly Quebec context, because the pharmaceutical and agri-food industries in Quebec have certain differences, particularly in terms of their composition of very small, small and medium-sized companies. (For example, the Quebec agri-food industry is fragmented into a number of very small companies (VSEs) and small and medium-sized enterprises (SMEs), while the pharmaceutical industry is made up mainly of very large international companies).

As mentioned above, the pharmaceutical and agri-food industries share certain similarities. On the one hand, pharmaceuticals and agri-foods both have potential benefits and harms at individual (nutrition, treatment, pleasure) and societal (cultural, economic) levels. On the other hand, the pharmaceutical and agri-food industries are both highly lucrative and have a definite influence at political level (24,25). Finally, nutritional research, like pharmaceutical research, is partly funded by the private sector: in 2000, 62% of pharmaceutical research in the United States was funded by the private sector (26) and in 2013, in the same country, private sector funding accounted for more than 70% of nutritional and agri-food research funds (27). In Quebec, the private sector, including NPOs, is the second largest source of research funding (all fields combined) after federal and provincial funding agencies (8). Although the proportion of private research funding is lower in Quebec than in the United States, pharmaceutical and nutritional research are also supported by their associated industries. In pharmaceutical research, for example, there is a public-private funding partnership between Merck Canada and the Institute for Research in Immunology and Cancer (28). In nutritional research, partnerships can take the form of philanthropic chairs, such as the Saputo Chair in Biomedical Valorisation of Dairy Products at the Université de Montréal (29), or industrial chairs, such as the NSERC Industrial Research Chair in Metabolic Activities and Functionality of Bioprotective Lactic Cultures (METABIOLAC), whose private partners include the meat processing company Olymel (30). There are several examples of the types of research collaborations and collaborators, and research partnerships and partners. As described below, this has an impact on the COI risk.

The primary objective of the pharmaceutical industry is to develop and make available medicines. However, from the point of view of good corporate citizenship (i.e., the fulfilment of a company's roles and responsibilities to society) this is not its only objective. In this respect, pharmaceutical companies must make a profit, obey the law, act ethically and philanthropically (31). Quite often, however, the decisions and actions of the pharmaceutical industry show that it seems to attach more importance to the duty to make a profit than to the other facets of good corporate citizenship. The same is true of the agri-food industry.

The pursuit of profit leads the pharmaceutical industry to take actions that are reprehensible to say the least, if not reprehensible, ranging from intense/unfair lobbying to deceptive marketing. Similarly, the pharmaceutical industry tries to influence researchers and control research results by various means, such as funding scientific and educational activities (e.g., sponsored conferences or speakers) with the unavowed aim of biasing research and clinical practice (32). This same type of influence strategy can be (is) used by the agri-food industry to bias nutritional research and practice. A company sponsoring a conference on a subject related to its interests (e.g., a sports drinks company funding a conference on sports nutrition) (33), does so in a self-interested manner and in so doing uses a strategy of influence.

One of the strategies used by pharmaceutical companies to bias research is to emphasise the benefits rather than the risks of their products. This takes the form of not publishing negative results, rigging studies to favour positive results and restricting the academic freedom of researchers conducting research on a pharmaceutical product — although this last stratagem is used less and less (34). These strategies could be (and are) used by the agri-food industry to bias nutritional research in its favour. One example of a strategy used by the industry to bias research to its advantage is the funding of studies that focus on health risks other than those associated with the products it sells (35). Coca-Cola, which is an agri-food multinational comparable to the giants of the pharmaceutical industry, used this type of strategy by setting up the Global Energy Balance Network (GEBN), a non-profit organisation (NPO) whose mission was to fund and conduct research into the causes of obesity. The organisation, backed by Coca-Cola, argued that too much attention was being paid to calorie intake rather than physical activity in obesity prevention discourse. However, several studies have shown that calorie intake has a greater effect on the risk of obesity than lack of physical activity. Coca-Cola, via GEBN, was trying to shift the research and debate on the causes of obesity in its favour, i.e., by emphasising lack of physical activity rather than diet.

The pharmaceutical industry's reprehensible actions have had the effect of shaking, and in some cases outright shattering, the academic world's confidence in it. Editors of scientific journals have openly criticized the pharmaceutical industry's methods: the number of editorials denouncing these practices has increased, some scientific journals (such as the *British Medical Journal*) have considered banning the submission of articles written by industry authors, others (such as the *Lancet* and the *New England Journal of Medicine*) refuse to publish journal articles written by industry authors, and some conferences refuse to allow pharmaceutical companies to present their research results (36). This suspicion, which has also spread to the general public via the media, could be transposed to nutritional research, as exemplified by reports in the *British Medical Journal* (22) and *PLOS Medicine* (23). Lastly, the consequences of research bias go beyond the academic sphere, since scientific data is used in the development of public policy and is widely reported in the media, and research bias can influence people's behaviour and even have harmful consequences for public health (37).

In short, the literature on pharmaceutical research partnerships tells us that the pharmaceutical industry's strategies for biasing research are numerous and that the consequences can be serious. Given the similarities between the pharmaceutical and agri-food sectors, it is possible to extrapolate this information from one sector to the other. Just as those involved in pharmaceutical research must be cautious about collaborating with the pharmaceutical industry, those involved in nutritional research must also be cautious about

collaborating with the agri-food industry, whose influence strategies may be similar to those of the pharmaceutical industry.

Factors conducive to the emergence of COI in nutritional research

The agri-food industry can use various strategies to bias nutritional research, but academic collaboration with this industry is in many ways important, if not essential, for the pursuit of research activities. However, such collaborations pose a COI risk for researchers and research institutions. Several factors increase this risk: 1) the lack of public funding; 2) the type of financial partner and its interests; 3) the intensity of the links of interest; and 4) personal interests. These factors will be described in the following paragraphs.

1) Lack of public funding

The lack of public funding for nutritional research (and research in general) means that researchers are less likely to collaborate with the private sector. In the United States in 2009, public funding for nutritional research amounted to US$1.5 billion. In comparison, funding for nutritional research by the agri-food industry reached US$12.4 billion in 2013 (38). As far as we know, there is no specific data on funding for nutritional research in Quebec. In general, in the Quebec research community, the main source of funding comes from federal and provincial funding agencies. Research funding from private partners (e.g., companies in the agri-food industry in the case of nutrition research), public partners (e.g., government agencies or ministries) or NPOs is the second largest source of research funding in Quebec[3] (8). Private sector research funding may be monetary or in kind, for example through access to data or exclusive knowledge, or the provision of research infrastructure.

Competition between researchers for government grants and the conditions under which they are awarded may encourage them to apply for or accept funding from private companies (8). For example, the success rate for a grant from the Canadian Institutes of Health Research (CIHR), which was close to 38% in 2000-2001, was only 14.3% in 2014-2015, and is expected to reach only 10% in 2017 (39). Thus, the lack of public money invested in research leads to a low rate of researchers obtaining grants, which means that in some cases researchers supplement their research budgets with private funds. On the other hand, some grants favour research projects that have the potential to meet entrepreneurial needs or create commercial spin-offs. Partnerships with industry may even be a condition for the award of certain grants, such as compulsory matching funding, which encourages researchers to establish collaborations with the private sector. By doing so, researchers put themselves at risk of financial COI. However, as we shall see in the following sections, the risk of COI is not uniform for all collaborations between researchers and industry. It varies according to the type of partner, its mission and interests, and the strength of the collaborative link established.

2) Type and interests of financial partner

The agri-food industry is made up of several types of players: producers, processors, producer groups, manufacturers, distributors, suppliers, the food (catering) and restaurant trades, franchisors, retailers and their associations, food advertisers, public relations companies and the specialist publications industry. The primary interest of these players may be more or less

[3] These are, in Quebec, the Fonds de Recherche du Québec — Santé (FRQ-S), the Fonds de Recherche du Québec — Nature et Technologie (FRQ-NT) and the Fonds de Recherche du Québec — Société et culture (FRQ-SC), and in Canada, the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), the Social Sciences and Humanities Research Council (SSHRC), the Canada Research Chairs (CRC) and the Canada Foundation for Innovation (CFI).

distant from that of nutritional research, depending on their position in the production chain and on the agri-food market (38). The more the interests of the funding partner diverge from those of the researcher or research institute, the greater the risk of COI. It is therefore important to consider the interests of the potential partner in order to assess whether they might coincide with those of the research in order to judge the acceptability of a possible collaboration (discussed in part 2 of the document).

For example, "some companies focus on a certain number of products that are harmful to health in order to increase their sales, while others offer a variety of products and demonstrate their attachment to values other than financial gain" (38). Thus, some companies may have interests that are closely aligned with those of the researchers (e.g., their mission is to sell food considered to be "healthy", and they therefore attach importance to the effect of their products on health), in addition to having interests similar to those of other industry players (i.e., financial interests). A collaboration with a processed products company A with a branch of so-called "healthier" products would be more acceptable than another with a company B producing and selling strictly only products that have been shown to be harmful to health. To a certain extent, the interests of company A could be reconciled with those of research, which would be unlikely for company B. In any case, it is worth being vigilant, as collaboration with a private company may improve its image but damage that of the research institution or the researcher. We will discuss the risk of damage to the reputation of the researcher/research institution and loss of public confidence below.

On the other hand, although we have so far focused on collaborations with the agri-food industry, researchers can also receive funding from NPOs.[4] It is important to note that a collaboration with an NPO, like a collaboration with industry, may pose a COI risk. Here again, this risk varies according to the type of NPO and its mission. In the literature, a distinction is made between NPOs with a public interest ("public interest non-governmental organization"; PINGO) and those with a business interest ("business interest not-for-profit organization"; BINGO). BINGOs are NPOs that are either founded by companies, represent the interests of industry or are linked to industry (40). PINGOs, on the other hand, have public interests in that their mission is to promote or protect the interests of the public (e.g., health, education, rights, etc.) (41). It may be difficult to classify an NPO as a BINGO or a PINGO; these distinctions are not absolute. For example, the Coca-Cola Foundation's three priorities of empowering women, providing access to clean water and improving community well-being (42) alone would qualify it as a PINGO. However, its intrinsic links with the agri-food industry, and more importantly with a company that produces high-sugar drinks, gives it the attributes of a BINGO.

The risk of COI for a nutrition researcher is higher when collaborating with a BINGO than with a PINGO. This is because the latter more often have interests or objectives that may align with those of a nutrition research project, such as understanding the effect of a nutrient on the risk of developing a particular disease. However, all NPOs, including PINGOs, may themselves receive funding from the agri-food industry and, as such, they may have interests (e.g., promoting the interests of their members, seeking funding to ensure their operation) that are in tension with their primary interests and those of the research. Finally, funding for nutritional research by NPOs can be used by the agri-food industry to bias research (as was the case with GEBN and Coca-Cola).

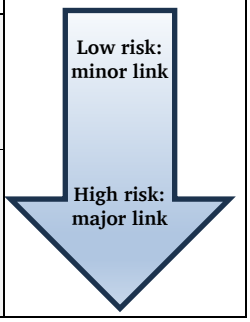
[4] A foundation is a form of NPO.

3) Intensity of ties of interest

On the other hand, collaborations between researchers and the agri-food industry extend over a spectrum where they can be more or less strong (see Table 1). The risk of COI increases with the level of collaboration between a researcher and the private sector, because the more intimate the collaboration, the greater the level of dependence and reciprocity, as well as the risk of conscious or unconscious bias on the part of the researcher towards the financial partner (43).

Donations are the first type of collaboration. Sometimes anonymous and sometimes associated with advertising, they take the form of monetary or material contributions from private companies. Collaboration can also take the form of sponsorship, which is more associated with commercial relationships. These are specific to a particular project and have the clear objective of promoting the sponsor in order to polish its public image. When collaborations take the form of platforms for exchange and discussion, they consist more of a dialogue between the players involved. There is a transfer of ideas, but not of money. When the collaborating players commit to joint services, these may take the form of an alliance or partnership. Alliances take shape through the drafting of agreements in which all the partners undertake to respond to complex problems (8). Partnerships, on the other hand, are the most complex forms of collaboration, where several players from the private and public sectors join forces with a view to achieving their respective objectives. As Simic points out, "[t]he main characteristic of this [type of collaboration] is that it includes greater commitment, shared responsibility and decision-making, and a diversity of actors with different skills and resources" (8).

Table 1: Levels of risk associated with different types of collaboration between the nutrition research community and the agri-food industry

<table>
<tr><th colspan="4">Type of collaboration with industry and level of risk</th></tr>
<tr><th colspan="2">Based on the nature of each partner's contribution</th><th>Based on the importance of collaboration in the mission of organisations</th><th>Level of risk</th></tr>
<tr><td>Donations</td><td rowspan="2">Contributions in cash; contributions in kind of goods and services</td><td>Philanthropic relations</td><td rowspan="5"> 
</td></tr>
<tr><td>Sponsorship</td><td rowspan="2">Transactional relationships</td></tr>
<tr><td>Exchange or discussion platforms</td><td>Dialogue</td></tr>
<tr><td>Alliance</td><td rowspan="2">Joint service</td><td rowspan="2">Integration/transformation relations</td></tr>
<tr><td>Partnership</td></tr>
</table>

Adapted from Simic (8) and Healthy People and Communities (44)

Furthermore, even if the collaborative link is weak, and therefore so is the risk of COI, the appearance of COI may cause a certain distrust or loss of public confidence in the research partner. This consequence of COI is discussed later in the text.

4) Personal interests

It is well known in the academic world that the quest for recognition is characteristic of many researchers. The desire to be recognised as an expert or even a leader in one's field of research is a normal (even encouraged!) and common interest in the research profession (45). However, like a financial interest, it can get in the way of the primary

interest of the research (3). By attaching more importance to their potential celebrity than to the scientific value of their research, researchers are putting themselves in a COI situation. The greedy quest for recognition can have a range of consequences for a researcher's behaviour, from varying degrees of bias in the interpretation of research results to outright scientific fraud.

Furthermore, personal interests, such as ideological biases, can influence a person's perception of a research collaboration and cause a COI. For example, an unfavourable prejudice against "nasty multinationals" is likely to be reflected in an unfavourable judgement of any collaboration with a multinational company, without even having assessed all the elements of the context of the potential collaboration. In other words, the rejection of any collaboration with a multinational enterprise without having considered its risks and benefits could constitute a personal COI if this rejection was motivated by a tenacious prejudice. On the other hand, a COI caused by a favourable prejudice towards, for example, a local company, would entail a risk of assessing too quickly its mission, values and interests, which could run counter to those of the research institution. The result could be a harmful collaboration for the academic collaborator.

Ideological bias

If certain personal interests among scientists can pose a COI risk (e.g., the desire for academic advancement and a firm belief in an ideology), is this the case for all personal interests (e.g., personal experiences, political or religious beliefs, type of training, etc.)? Human beings tend to attribute ethical behaviour to themselves and to be blind to their own biases. In the context of scientific research, this belief is accentuated by that of the researcher's objectivity. By believing themselves to be totally objective and immune to bias, researchers actually make themselves more vulnerable to it (46). However, it is increasingly recognised that scientists cannot be perfectly objective, because — like all individuals — they come from a particular culture and socio-economic background, have certain beliefs, receive different types of education, etc. In short, personal characteristics and beliefs can influence the way in which research is conducted. In short, researchers' personal characteristics and beliefs can influence or bias their research, causing unconscious bias.

It seems exaggerated to think that all the interests (personal characteristics, beliefs, life experiences) of a person can be considered as major links of interest that can be translated into COI. Could we really list all an individual's interests and measure the biases caused by them? This seems difficult, if not impossible, and potentially counterproductive. Indeed, as mentioned above, several studies have demonstrated the association between financial COIs and systematic biases. An overzealous assessment of personal interests could obscure the presence or importance of financial COI, which are certain to cause systematic biases that can have repercussions in people's lives, via science-based public policies (47).

In short, there is no threshold for defining whether a personal interest is likely to cause an COI. However, the ideological biases of researchers can be balanced out if the opinions of several researchers are taken into account (47). Knowledge of one's own interests (and even biases) can partly reduce the risks to objectivity associated with COI of a personal or ideological nature.

The erosion of public trust: a major risk associated with COI

We have already discussed the risk of bias associated with COI in nutritional research. This risk primarily concerns the scientific community, which builds new knowledge on that created by other researchers. It then indirectly concerns governments and the general public,

for example when research is translated into recommendations, guidelines and public policies. However, there is a risk associated with COI that directly concerns the relationship between the public and researchers, as well as the relationship between researchers themselves, i.e., the erosion of trust between the public and the scientific community.

While collaboration between the private and scientific sectors can improve the image of the private partner, the same cannot be said for the scientific partner, for several reasons. Firstly, the revelations about the tobacco companies' concealment of data on the harmful effects of their products have raised public awareness of the risks of bias involved in the private funding of scientific studies (48). Furthermore, as discussed above, the pharmaceutical industry's strategies for influencing research have resulted in researchers, editors of scientific journals, journalists and the general public becoming suspicious of studies funded by the industry (36). This mistrust has already been transposed to nutritional research funded by the agri-food industry. The funding of studies by the agri-food industry can call into question, in the eyes of the public and the scientific community, the methodological validity, conclusions and credibility of the researcher in charge of such studies.

Secondly, scientific partnerships with industry are often perceived more negatively, and those with NPOs more positively. For example, in a study assessing the perceived legitimacy of a research partnership, a (hypothetical) partnership with the Kellogg company was more negatively perceived than another (also hypothetical) partnership with the American NPO Union of Concerned Scientists (UCS). A research partnership with Kellogg was three times more likely to elicit a negative comment from the research participants (university students) than a partnership without this company (i.e., either with an NPO and/or a government body and/or a university), because it was felt that a partnership with the cereal company would have the effect of making the conduct of the research less fair. Partnerships with a government body or university, on the other hand, had neither a positive nor a negative effect on the perception of their legitimacy (49).

Thirdly, one of the factors that could potentially exacerbate popular cynicism about industry-funded research is "nutritional scientism". Nutritional scientism describes the situation in which scientific opinion is considered to be the opinion par excellence by the population (50). By placing an inordinate value on the science of food in relation to its social and cultural attributes, the realisation that science can be biased by COI can increase popular cynicism towards it. Nutritional scientism increases people's disappointment with science and scientists when they realise that scientists have lacked integrity. The importance of public confidence in nutritional research should not be underestimated in the context of public health. If there are data demonstrating the benefits of consuming a particular food and this is encouraged by various policies, but the public is distrustful of the information, public health measures will have a reduced impact.

The loss of confidence on the part of the public, the scientific community and key players in the field, which is often justified in the presence of COI, can however have repercussions on well-done research. Science produced with private funds is not *always* biased, and the cynicism engendered by research COI can lead to the rejection of quality studies (8). Similarly, an industry-funded study can lead to a loss of confidence in a researcher or research institute's research as a whole, regardless of whether their other research is funded by industry (15). Finally, the mere appearance of COI can lead to public suspicion; there is a risk that valid scientific results will be rejected, for example, on the basis of past collaborations between the academic research community and the agri-food industry (51).

In short, COI can have a negative impact on popular and scientific opinion, and at the same time affect the social acceptability of a research collaboration. However, compliance with the minimum conditions of social and ethical acceptability of a collaboration between the private and public sectors (e.g., code/policy for responsible conduct of research by research centres or granting bodies) guarantees the credibility and legitimacy of the scientific partner. These findings support the need to properly manage COI resulting from collaborations between the nutrition research sector and the agri-food industry.

Disclosure risk

Generally, the first step in managing a COI is disclosure (the COI management steps are developed below). However, disclosure can have unexpected impacts. In fact, disclosure can have a positive or negative influence on the message of the person with the links of interest:

> On the one hand, disclosure may dissuade [persons with interests] from giving biased advice by increasing their concern that appraisers (now aware of [the interests] as a result of disclosure) will disregard advice that is extreme or associated with motives that are considered corrupt and seem questionable. On the other hand, [persons with ties of interest] may be tempted to give an even more biased opinion and to exaggerate it in order to counter the decrease in its value in the eyes of the appraisers; this strategic exaggeration is like expecting that disclosure will lead the audience to cover its ears and thus compensate by shouting even louder (52).

Furthermore, disclosure can increase or decrease the trust of others (the estimator, in the quote above). For example, if a person considers that a COI necessarily leads to lying, their trust in a collaborating entity that they considered trustworthy *a priori* will decrease. Conversely, the person who declares his COI may be judged to be more honest than the person who does not, giving rise to what is known as "blind trust" (52). In short, the disclosure of links of interest can have an unpredictable influence both on the message conveyed by the person who has these links and on the interpretation of the message by the person who has to judge its value.

Although it may prove impossible to predict the behaviour and reactions of those with links of interest and those who must judge them (including the public), disclosure is essential to a transparent COI management process, the benefits of which can only outweigh the long-term disadvantages.

Advantages of collaboration between the private and scientific sectors

Collaboration with the private sector does not only entail risks and disadvantages. Firstly, despite the inherent risk of financial COI and research bias, funding nutrition research by the agri-food industry is an advantage for researchers in a context where federal and provincial research grants are insufficient. In particular, the diversity of funding sources enables researchers to maintain the expertise and knowledge developed in their laboratories (53).

Secondly, collaboration between the private sector and the university research community can facilitate the transfer of knowledge between these two communities and the development of research expertise. It can also encourage the application of research results and open up professional and academic opportunities (8). Like mutualism, collaboration between the private sector and the university research community brings together two groups of players who benefit from this relationship, with the benefits being reciprocal when the collaborations are well managed. By way of illustration, while the agri-food industry

possesses knowledge and infrastructures that can be useful to researchers, the latter possess knowledge and use or develop technologies that can be of great use to private companies in this field. More generally, research funds (and other resources) granted by industry can contribute to the advancement of knowledge in nutrition and possibly to improving the health of the population (if the research is not biased, it goes without saying). Scientific discoveries in nutrition can, for example, help industry to improve the nutritional composition of its products and enhance its brand image.

Thirdly, collaboration between the private and research sectors broadens the range of expertise that can be brought to bear on research, while promoting interdisciplinarity and the achievement of objectives that could not have been achieved by individual researchers (8).

Summary

In the current context of nutritional research, the presence of links of interest and COI, the seriousness of which may vary (from acceptable to unacceptable), is inevitable. It is therefore important to be pragmatic and to set aside ideologies (without compromising one's integrity or academic freedom) in order to really work towards the objective (i.e., public health). In the light of the risks and benefits of partnerships and/or collaborations between the nutrition research community and the agri-food industry, and understanding that certain COI are inevitable, the question to be asked is not how to avoid all COI, but rather how to properly manage those that cannot be avoided.

Recommendations

In the absence of detailed policies for the management and disclosure of COI that are adapted to the reality of the members of an institution, it was illustrated in the previous section how an institution puts itself at risk of ethical abuses that can erode, on the one hand, the confidence of its members and of the public (54) in it and, on the other hand, its credibility with the various key players in its sectors of activity. This section presents concrete recommendations — inspired by the best practices documented in the scientific literature — that have been proposed to the EAC to help it manage the links of interest within the Observatory's formal governance structure. These recommendations were formulated with a view to promoting the Observatory's institutional integrity, i.e., the coherence between the effects of its actions and its mission, values and objectives (8). As desired by the Steering Committee, the implementation of these recommendations would make it possible to ensure ethical and transparent governance of the Observatory, a key element in ensuring its credibility and, ultimately, its ability to "[b]e a recognized source of reference at the Canadian and international levels on issues related to the quality of the food supply and consumer behaviour towards healthy eating." (55)

This section is divided into two parts. First, a process for declaring and managing members' links of interest is proposed. Secondly, recommendations are made on how to manage collaborations with the agri-food industry, which are beneficial to the Observatory since they have the potential to make a positive contribution to the collective effort to improve the health of populations. In these two sections, we will refer frequently to the Observatory's "primary interest". This is the Observatory's primary interest, the one with which none of the interests of its members or of an agri-food industry should conflict or contribute to being neglected or perverted. Otherwise, the result would be a form of institutional corruption. This can occur when entities with different and/or opposing primary interests collaborate and the mission of one of the two entities is perverted (8), negatively influencing the quality

of its internal structure and the public's confidence in it (15). For the purposes of this document, it is considered that the primary interest of the Observatory is to be able to:

> To monitor and observe changes in the food supply in order to generate new knowledge and act collectively to improve its quality and accessibility with rigour, transparency and objectivity. All this, while promoting the mobilisation of key players in the field and the social usefulness of the Observatory (55).

Process for declaring and managing conflicts of interest

An ethical process for the disclosure and management of conflicts of interest of Observatory members was proposed to the EAC. This helped the committee to develop its process for assessing declarations of interest and to draw up guidelines for its application. It is divided into three parts: 1) the **declaration** of interests from which situations of conflict of interest are likely to emerge, 2) the **evaluation** (analysis and assessment) **of the risk of** the interests disclosed and 3) the **management of** links of interest judged to be risky and conflicting.

1) Declaration of interests

On taking up their duties and in accordance with the declaration form drawn up by the EAC (56), all members and all individuals directly linked to the Observatory's activities complete a detailed declaration of interests form. This must be completed when a member takes up his or her post and updated according to the professional, academic and personal activities of each individual. It is updated annually or on an ad hoc basis when a new interest arises during the year that could not have been foreseen (56,57). In all cases, the interests declared are re-analysed and, if relevant, they are again subject to a management plan drawn up by the EAC (56).

In the declaration form, all relevant information regarding an individual's *actual*, *potential* and *apparent* COI must be collected in a precise manner in order to truly mitigate the biases that may result (58). For example, if there is a question of a financial link of interest arising from travel expense reimbursements, a reader must be able to identify the amount in question, which company was the debtor, in what year the money transfer took place and, if applicable, who benefited from it (e.g., only the individual or the individual and his family), etc. It is important to note that disclosure of these three types of interest (*actual, potential* and *apparent*) is essential as the appearance of COI can erode the confidence of third parties and affect the reputation of the individual and the institution to which he is linked as much as actual or potential COI. They must therefore all be declared and subject to the same ethical standards.

It should be noted, however, that when it comes to non-financial links of interest, the extent of disclosure is likely to raise ethical and confidentiality concerns. Indeed, it can sometimes be difficult to differentiate between non-financial personal information whose disclosure is necessary and that which is not, and where the requirement for disclosure constitutes an invasion of the individual's privacy. As Bero points out, disclosure of non-financial interests is sometimes trivial. When researchers publish research or discuss their work in the public sphere, "their training, their institutional and academic affiliations and their intellectual and theoretical positions" (13) are public.

Finally, although filling out such a form may seem laborious the first time it is completed, it remains essential to ensure the transparency of the Observatory. As mentioned in the first part, studies tend to show that even seemingly insignificant benefits can favourably influence an individual's judgement of a company (e.g., compensation associated with participation in

a scientific activity, access to a database, payment of travel expenses, etc.) (59). It is also important to remember that completing this form is only the first step in a transparent process for declaring and managing interests, since these forms alone are insufficient. Once completed, the forms must be subjected to a risk assessment mechanism for the interests disclosed. Such a mechanism makes it possible to identify problematic interests that require intervention by the EAC to mitigate them and prevent them from threatening the Observatory's ability to pursue its primary interest (see above).

2) Assessment of the intensity of declared interests

The declaration forms make it possible to identify the links of interest between members and other people directly involved in the Observatory's activities. In order to prevent any of these interests from affecting their impartiality (10) and potentially the Observatory's credibility or independence, the forms are then subjected to a rigorous review process in order to identify any potentially conflicting major links of interest. After exploring the various factors that influence the intensity of a conflict of interest, this section presents the analysis guide that was presented to and implemented by the EAC to promote a uniform assessment of the declaration forms and to facilitate decision-making on the third stage of the process, i.e., the management of major conflicts of interest that give rise to a presumption of conflict. The guide puts forward uniform and standardised criteria for assessing the files. It has supported the Observatory in setting up a transparent and consistent process for assessing disclosed interests. While offering a general framework for application, such a guide also makes it possible to modulate the analysis of the files by taking into account the particularities of each individual, thanks to the various qualitative criteria considered (10).

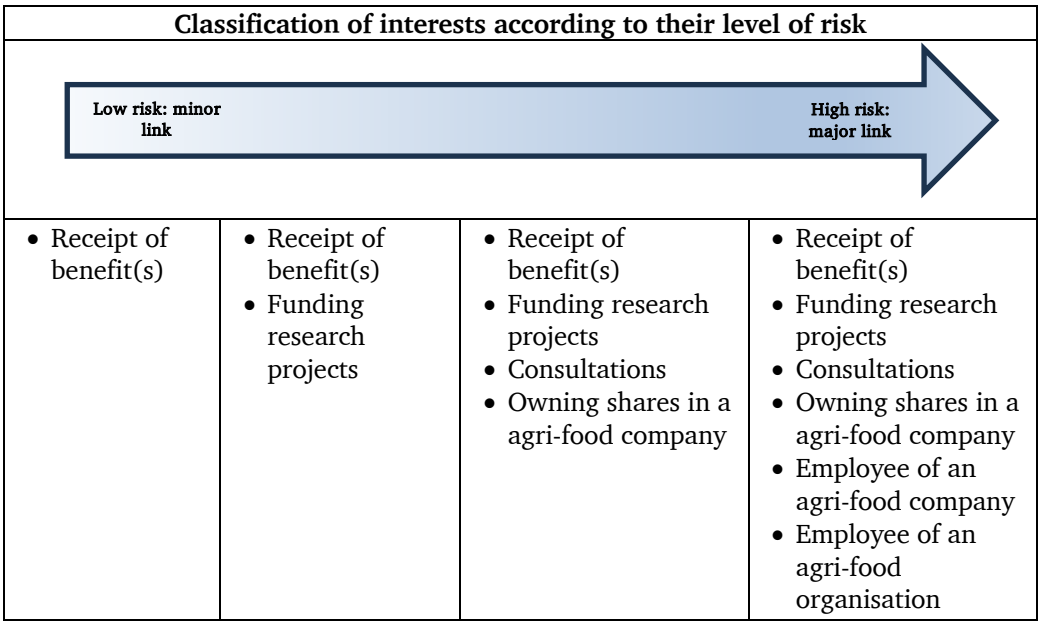
The literature generally mentions that it is essential to go beyond the disclosure of interests in order to mitigate their harmful effects (47). However, in line with this observation, guides or criteria are rarely proposed to provide a framework for assessing disclosed interests and ultimately facilitating their management. The proposed grid is therefore mainly based on two analysis guides developed in France to assess the interests disclosed via public declarations of interest by members or close collaborators of the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) and the Haute Autorité de Santé (HAS) (see Appendices 1-2). ANSES is a French agency whose main remit is to provide the scientific and technical support necessary for the State to make informed decisions on health matters (60), while HAS is an independent public institution with a scientific vocation, which aims to promote the regulation of the French healthcare system (61). ANSES and HAS are similar to the Observatory in that they have committees similar to the EAC. Their mission is also to encourage an ethical governance structure, in particular by preventing COI and managing them where necessary (55,60,62). With this in mind, their committee responsible for ensuring the transparency of the organisation has drawn up guides for declaring interests and managing conflicting interests.

The intensity of the relationship

Figure 1 shows the extent to which not only do not all links of interest immediately present the same level of risk (63), but that the risk inherent in certain interests may itself vary. Some may always be obvious and very risky by their very nature, such as being an employee of an agri-food company whose interests are likely to be significantly affected by the Observatory's activities (10). Other links of interest may fluctuate more in intensity: sometimes being a minor link at low risk and, in other circumstances, being considered a major link of interest at high risk. For example, the level of risk associated with having one's research activities funded by the private sector may be much greater if it involves large sums

of money than that associated with being a consultant or holding shares in an agri-food company (43). This fluctuation can be explained by the various factors that vary the intensity of the link of interest.

Figure 1. Assessment of the level of risk of the disclosed interest according to its intensity


Classification of interests according to their level of risk
Low risk: minor link
High risk: major link
• Receipt of benefit(s)
• Receipt of benefit(s)
• Funding research projects
• Receipt of benefit(s)
• Funding research projects
• Consultations
• Owning shares in a agri-food company
• Receipt of benefit(s)
• Funding research projects
• Consultations
• Owning shares in a agri-food company
• Employee of an agri-food company
• Employee of an agri-food organisation

Adapted from Newton (43)

Here are the different factors that influence the intensity of the link of interest:

- The **frequency of the relationships** from which this link emerges: are they occasional, regular or frequent? (11) The more frequent the relationships, the more the link will be considered to be major and at high risk of conflicts of interest.
- The **amount or level of benefits** received: if they are financial or material, how much are they? If they are non-monetary, what is their level? If they are non-monetary, what is their level? (11) The higher their amount or level, the more the link will be considered major and with a high risk of conflicts of interest.
- The **temporal dimension of the links**: are they old, recent, permanent? (11) The more recent the link of interest, the higher the risk. The same applies to permanence. The reverse is also true: the older the relationship, the lower the level of risk, since the intensity of a relationship of interest usually diminishes over time. Thus, the evolution of a "major interest relationship" into a "minor interest relationship" can occur when a reasonable period of time has elapsed (57).
    - *But what is a reasonable period of time to consider that the intensity of a link has faded?* The answer depends essentially on the discretion and vocation of each entity or institution. It therefore varies slightly depending on the context (64). In France, for example, according to the decree on the public declaration of interest and transparency in public health and health safety, all links of interest must be declared if they occurred in the five years preceding the declaration (65). In the case of medical journals, Fontana argues that the relevant period is the 3 years preceding the submission of an article (64).

- *Can the intensity of a relationship of interest fade even within the so-called reasonable time period?* Regardless of the relevant time period chosen to differentiate between ties of interest that must be disclosed and those that do not, it is important to note that a tie of interest that is *a priori* major may no longer be so at the time the declaration form is evaluated (11), even if it occurred during the years deemed relevant to the declaration. For example, it is possible to consider that a major financial relationship fades more quickly into a minor relationship than a non-financial relationship of interest since, generally speaking, it is easier to break and does not usually commit the declarant to a lasting relationship (57). To this end, the HAS has determined that at least three years must generally elapse before downgrading the assessment of the risk of an *a priori* major relationship of interest (11). Essentially, what must be borne in mind when determining these time periods is that, in order to preserve public confidence, it is always preferable to favour slightly longer time periods that lead to the declaration of as many links of interest as possible (66).

Grids for analysing declared links of interest

This sub-section presents the analysis guide presented to the EAC to promote uniform evaluation of the declaration forms and to facilitate decision-making on the third stage of the process, i.e., the management of major ties of interest that give rise to a presumption of conflict.

Direct or indirect links with an organisation, body or company in the agri-food sector (10,11,67)		
Links of interest to be declared	**Declared position and intensity of the relationship of interest**	
	Major	*Minor*
Possession of a financial interest in the capital of a company in the agri-food sector (listed or unlisted securities, shares, options, units or other financial assets).	Ownership of a **significant** proportion of the capital (= or > 5%) of a company in the agri-food sector likely to benefit or be penalised by the Observatory's activities.	Holding a **negligible** share (< 5%) of the capital of a company likely to benefit or be penalised by the Observatory's activities.
Current or past participation (last 5 years) in a decision-making body of an organisation, body or company in the agri-food sector.	Member, paid or unpaid, of the board of directors or other decision-making bodies of an organisation, body or company in the agri-food sector **likely to** benefit or be penalised by the Observatory's activities.	Member, paid or unpaid, of the board of directors or other decision-making bodies of an organisation, body or company in the agri-food sector that is **not likely to** benefit or be penalised by the Observatory's activities.
Current or previous experience (last 5 years) as a consultant, advisor or expert for an organisation, body or company in the agri-food sector.	**Regular** consultancy, advisory or expert activity, **with or without remuneration**, for an organisation, body or company in the agri-food sector **likely to** benefit or be penalised by the Observatory's activities.	**Occasional** consultancy, advisory or expert activity, **with remuneration**, for an organisation, body or company in the agri-food sector **likely to** benefit or be penalised by the Observatory's activities.
		Occasional unpaid consultancy, advisory or expert activity for an organisation, body or company in the agri-food sector **likely to** benefit or be penalised by the Observatory's activities.

		Regular or irregular consultancy, advisory or expert activity, **with or without remuneration**, for an organisation, body or company in the agri-food sector that is **not likely to** benefit or be penalised by the Observatory's activities.
Current or past (last 5 years) paid or unpaid work in a body, organisation or industry in the agri-food sector (self-employed, paid or voluntary work).	Activity within an organisation, body or company in the agri-food sector **likely to** benefit or be penalised by the Observatory's activities.	Activity within an organisation, body or company in the agri-food sector that is **not likely to** benefit or be penalised by the Observatory's activities, but whose activity, objectives, techniques or products are related to the Observatory's field of competence.

Receipt of a benefit, whether in kind or in money, from a person, organization, body or business operating in the agri-food sector for a favour or service rendered (10,67)		
Links of interest to be declared	**Declared position and intensity of the relationship of interest**	
	Major	*Minor*
Articles written and presentations made (within the last 5 years) at congresses, conferences, symposia or training courses organised or funded by organisations, bodies or private companies in the agri-food sector.	Intervention (writing of articles, congresses, conferences, symposiums, training, etc.) for which an individual is **remunerated or compensated (e.g., covering the extended stay expenses or travel expenses of a non-participating companion**) by an organisation, body or company in the agri-food sector **likely to** benefit or be penalised by the Observatory's activities.	Intervention (writing articles, congresses, conferences, symposiums, training, etc.) for **which** an individual is **not remunerated or compensated (e.g., covering registration or travel expenses**) by an organization, body or company in the agri-food sector **likely to** benefit or be penalized by the Observatory's activities (10.67).
		Intervention (writing articles, congresses, conferences, symposiums, training, etc.) for which an individual **is remunerated or compensated (e.g., covering registration or travel costs**) by an organisation, body or company in the agri-food sector that is **not likely to** benefit or be penalised by the Observatory's activities.

An interest in a family member, friend or current professional relationship that has placed you, or is likely to place you, in a situation of real, potential or apparent conflict of interest (10,67)		
Links of interest to be declared	**Declared position and intensity of the relationship of interest**	
	Major	*Minor*
Close family members, friends or work colleagues who are employees and/or have a financial interest in a body, organisation or company in the agri-food sector.	Close family member, friend or work colleague who is an employee or shareholder of a significant part of an organisation, body or company in the agri-food sector likely to benefit or be penalised by the Observatory's activities.	Member of the close family, friends or close work colleague shareholder of a negligible share of an organisation, body or company in the agri-food sector likely to benefit or be penalised by the Observatory's activities.

		A close family member, friend or work colleague who is an employee or shareholder of a significant part of an organisation, body or company in the agri-food sector that is not likely to benefit or be penalised by the Observatory's activities.

Other links of interest
Given the large number of links that can be declared, these will be analysed on a case-by-case basis.

3) Managing conflicting interests

The major links of interest identified — those whose level of intensity (or risk of COI) is high (11,57) — give rise to a kind of presumption of COI because of the reasonable doubt they raise about an individual's ability to demonstrate the level of impartiality and independence required by his or her function or status (11,57). However, once the links of interest likely to conflict with the primary interest of the Observatory have been identified, the EAC is responsible for drawing up a COI management plan (56).

Although these management strategies must be adapted to the reality of each declarant, they must be coherent and relatively uniform in order to ensure the transparency of the decisions taken by the EAC. This section presents various strategies for managing major links of interest that the EAC can use with both Steering Committee and Advisory Committee declarants in order to maximise the Observatory's ability to respect its primary interest as identified above.

Eviction of the Observatory

Where a relationship of interest of a member of the Observatory drastically conflicts with the primary interest of the Observatory and seriously affects — actually, potentially or in appearance — its ability to pursue its objectives, the EAC must, where circumstances permit, offer the declarant the choice of terminating the relationship giving rise to this conflicting interest or leaving office. Where circumstances do not allow the individual to terminate the relationship through which the conflict of interest arises within a reasonable period of time, the individual is obliged to cease his or her involvement with the Observatory (10). This management policy is consistent with the literature. Indeed, many authors advocate the complete exclusion of members whose major ties of interest seriously threaten the credibility and independence of the institution with which they are affiliated (68). However, it should be pointed out that some authors also argue that this does not mean that these individuals, once excluded, cannot be called upon to intervene on an ad hoc basis as advisers if their expertise is relevant to an issue, without taking part in the deliberations and without voting (59,68). Indeed, depriving oneself entirely of an expert's perspective can be more damaging than the COI as such (68). This is why the EAC has provided for such an exception to the *complete* exclusion of the expert.

This management strategy is considered at all times by the EAC, whether during the selection of members or during any update of the declaration of interests form, whether annual or ad hoc. In addition, in order to limit the situations in which it might be necessary to exclude a person collaborating with the Observatory, the EAC introduces a "moderating ticket" when it deems it appropriate, to ensure that a potential collaborator fulfils predetermined criteria (e.g., absence of links of interest with industry) and adheres to the values of the Observatory even before taking up his or her duties.

Limitation of member participation

In certain circumstances where the link of interest is of lesser intensity (e.g., is not permanent, dates back a few years, etc.), but the declarant's impartiality and independence are nevertheless likely to be eroded by his or her links of interest, the EAC may recommend that the declarant's participation be limited by his or her exclusion from the study of certain files, or by the suspension of his or her right to vote when the said files are on the agenda (10,11,59). To implement this management strategy, a table summarising all the links of interest of the members of each committee and the recommendations of the EAC is created and updated as and when the declaration of interest forms are updated. This summary table is made available to the person chairing the meetings of each committee. At the start of each meeting, the Chair will introduce any new links of interest between members or remind members of those that have remained unchanged since the last meeting. In light of the EAC recommendations included in the table, when the issues on the agenda require the role of one or more individuals to be limited, the chair invites them to withdraw from the deliberations or vote (11). Finally, it should be noted that excluding and limiting a member's participation is easier when the interest is "external" to the individual (e.g., relational or financial) rather than "internal", which cannot easily be dissociated from the individual (e.g., personal beliefs and experiences). While it is true that it is relatively easy to dissolve a financial COI (e.g., by divesting), this is much less obvious with non-financial COIs: an individual's personal beliefs and experiences cannot be eliminated (13).

The literature seems rather unfavourable to excluding or limiting a member's participation on the pretext of the existence of a personal non-financial COI (e.g., adherence to a certain ideology or line of thought). Such action seems problematic for several reasons. Firstly, to act in this way would diminish the multiplicity of viewpoints surrounding a scientific question and, by the same token, the debate of ideas (13). This is particularly problematic when we consider, on the one hand, that science has developed through disagreement and debate and, on the other hand, that experts with strong points of view on certain issues can be key contributors to heated scientific debates (69). Secondly, reducing the diversity of viewpoints involved in decision-making is, according to other authors, unfair. Doing so implies that those who are not excluded or whose participation is not limited are more "objective". In reality, however, they undoubtedly have other personal beliefs and experiences or "intellectual commitments" (47).

Ultimately, what seems to be the best strategy for managing this type of conflict is downstream, by ensuring from the outset that the members of the various committees have a variety of ideas and "intellectual commitments" that are in balance, and this is what the EAC does (69). Thus, when setting up a committee or selecting a new member to fill a vacancy, the EAC asks itself the following questions:

- What is the professional identity of each candidate? What is their discipline, education and training? Where were they previously employed? What is their field of research and theoretical perspective?
- What personal characteristics are relevant? How old are they? What is their ethnicity? What is their gender? What are their religious and political affiliations? (47)

In the light of these questions, and in order to encourage genuine intellectual diversity and diversity of opinion, the EAC encourages the selection of one candidate or another on the basis of the perspectives that are represented or under-represented (47).

Ensuring beneficial collaboration

Collaboration with private industries in the food sector or with NPOs may be acceptable as long as they are governed by rigorous COI prevention and management mechanisms, and the players involved comply with high ethical standards (8). The following sections provide an overview of the key elements that the Observatory now takes into consideration when working with agri-food players. They are mainly inspired by the writings of Corinna Hawkes, a renowned professor of Food Policy who is widely quoted when it comes to transparent collaborations with the industrial sector (44,70), and by a document created under the coordination of Yves G. Jalbert, former scientific advisor to the Institut national de santé publique du Québec (INSPQ), as part of an activity entitled *Collaborer ou non avec l'industrie agroalimentaire dans la lutte contre l'obésité?* held 26 November 2014 as part of the Journées annuelles de santé publique. These proposals, which the Observatory adopted, are based on key elements characterising any well-governed collaboration: specific identification of the roles and responsibilities of collaborators, adequate supervision of the results targeted and of the collaborator, identification and management of COI and transparency (71).

1) Carry out a preliminary risk analysis

From the outset, to assess the level of risk of a possible collaboration, the members of the Observatory are guided by the following two questions suggested by Hawkes:

1. Would working together enable us to achieve our objectives more quickly and effectively?
2. Do the interests at stake (of both parties) favour or threaten the achievement of the main interest and objectives of the Observatory? (72)

If collaboration makes it possible to achieve the Observatory's objectives more quickly and effectively but is detrimental to the pursuit of its primary interest, it is immediately rejected. Obviously, the same applies if the collaboration leads the Observatory to act in a manner contrary to its mission and to pervert its primary interest (73). This approach is crucial to maintaining the Observatory's credibility in the community. Collaborations whose acceptability is shaky from the outset are likely to erode public confidence and, by the same token, undermine their credibility (44). Not collaborating at the outset or withdrawing from a collaboration is therefore sometimes more desirable (44,47).

2) Determining the best type of collaboration

When collaboration with a private company is envisaged because it is likely to accelerate the achievement of the Observatory's objectives without harming its main interest, it is essential that the most desirable type of collaboration be clearly identified by the Observatory when it enters into communication with the private player (74). In this respect, the following question, proposed by Hawkes, arises: "What type of collaboration is most likely to contribute to the achievement of [the Observatory's] objectives without undermining its primary interest" (71).

As explained in the first part of the text, there are different types of collaboration with the agri-food industry. As Table 1 in the first section illustrates, depending on their format and implications, they vary in their degree of complexity and, by the same token, in their level of risk (44). In choosing a type of collaboration suited to the Observatory's needs, its administrators must bear in mind that the higher the level of apparent or real COI risk involved in the collaboration, the more the Observatory's credibility and independence are put to the test, and the greater the measures to prevent and manage COI must be so that its

ability to pursue its primary interest is not affected. Thus, as indicated in the Observatory's executive summary, partnerships must sometimes be reconsidered, or in some cases avoided, since to ensure its independence and credibility, no agri-food industry player should be "involved in the Observatory's decision-making governance" (75). In the light of the feasibility study, collaboration with the agri-food sector will be mainly transactional (5).

3) Defining roles and responsibilities

Once the most desirable type of collaboration has been chosen, the Observatory must clearly define the roles and responsibilities of each collaborating entity. This is a key factor in successful and effective collaboration (71). It is important that all collaborators are aware of their role, the scope of that role, what is expected of them and what is not, in order to be able to achieve the objectives targeted by the collaboration (71). The key question put forward at this stage is "Which collaborators are required to achieve the objectives and in which roles" (71).

4) Identify possible conflicts of interest

Once the collaborators required to achieve the objectives have been identified, the Observatory identifies the possible COI that may emerge from the collaboration. These may be real, potential or apparent. If there are no COI, it is possible to move on to the next stage. If a COI exists, the scope of the COI must be assessed. To do this, various questions are asked:

- What is the nature of the conflict of interest (real, potential or apparent)?
- What interests or responsibilities are in conflict?
- Which parties are directly involved in the conflict of interest?
- Are the interests or responsibilities important to the parties involved?
- Are reputations or credibility threatened or at risk?
- Is the organisation's independence compromised?
- How might the conflict of interest be perceived by people outside the organisation?
- What are the risks and potential damage to the organisation's health and well-being objectives?
- What other players may be affected by these risks and damage (76)?

In the light of these questions, if it is not possible to manage the COI adequately, collaboration ceases to be an option. If a management plan is possible, it is presented to the potential collaborator(s). It is then only possible to proceed to the next stage if the potential collaborator accepts the proposed management plan (see Appendix 3) (76).

5) Agree common objectives

Because of its social role, it is likely that the Observatory's objectives and motivations for initiating collaboration differ from those of its collaborators (5,71). These differences are normal. What remains essential for the success of a collaboration is unity around objectives shared by all collaborators. To maximise their effect, these must be "specific, measurable and realistic" (71). At this point, Hawkes indicates that the question that needs to be asked is: "What are the objectives, do they require collaboration with the private sector to achieve them, and how can they be articulated, achieved and measured with the collaborators we have" (71). Moreover, once there is a clear, precise and transparent agreement between the partners, it serves as a detailed contract that ensures the Observatory's integrity and independence, regardless of the type of collaboration advocated. Ideally, this agreement should not give the industry a say (i.e., the power to influence direction or decision-making) (8). This considerably reduces the chances of the Observatory being bound by

terms and conditions that could limit its independence and increase the risk of apparent or real COI, i.e., that are harmful to it and contrary to its primary interest (73).

6) Be transparent

Transparency is a key concept at all stages of the collaboration process with the private sector. If the content of the collaboration is not publicly accessible and explicit, there is a strong risk that it will arouse suspicion and affect public confidence in the integrity of the Observatory. Sometimes, it can be difficult for laymen to conceive to what extent two entities with prima facie so distinct interests can really collaborate on an equal footing (71). The Observatory therefore discloses the roles and responsibilities of each collaborator and any relevant information (e.g., value of contributions in cash or in kind, content/topic of exchanges and discussions). Moreover, it is interesting to note that access to this crucial information not only fosters the confidence of the public and the various players in the community in the Observatory (even though disclosure can sometimes have the opposite effect, i.e., reduce public confidence), but also helps to educate the public about the benefits that can derive from transparent collaborations that truly have the well-being of the population at their heart (77). In this respect, a number of questions can be asked to ensure the transparency of the collaboration process with the private sector. In particular, "How can we best define and communicate roles and responsibilities to collaborators and the public in order to promote the effectiveness and legitimacy of the collaboration" (71).

7) Keeping a close eye on progress

Once the collaboration is in place, a monitoring mechanism is put in place to evaluate its performance on an ongoing basis. As well as maximising its effectiveness, such a mechanism fosters the legitimacy and credibility of the collaboration and, by the same token, public confidence in it. The general question the Observatory is asking itself at this stage is "What system should be put in place to closely monitor the state of collaboration, what indicators should be used to measure its effectiveness, and who should be responsible for exercising this monitoring role" (71).

Summary

In order to be transparent and ensure its ability to pursue its primary interest, the Observatory — via the Ethics Advisory Committee — has put in place a process for gathering information on its members' links of interest via a "Declaration of Interest" form that must be completed annually (or earlier if a new interest arises in the meantime), as well as a policy for assessing links of interest and managing COI. All of this will be based on the best practices identified in the literature and presented to the Board in the working document submitted in 2017. With regard to potential collaborations between the Observatory and various public or private organisations, the measures adopted by the Observatory based on the suggestions made in this chapter suggest that these are possible insofar as they in no way risk perverting the Observatory's primary interest, undermining public confidence in it or its credibility in the sector.

Conclusion

This chapter presented the COI reporting and management measures adopted by the Observatory based on the working document that was submitted in 2017 to the EAC to support it in pursuing its mission. Firstly, a summary of the literature was presented on COI in nutrition research and on good institutional governance in relation to collaborations between the agri-food industry and the nutrition research sector. This highlighted the fact that, in the current context of nutritional research, the presence of links of interest and COI

cannot be avoided. In this sense, it was emphasised how essential it is to adopt transparent and effective mechanisms for disclosing and managing links of interest in order to ensure the institutional integrity of entities whose primary interest is to ensure the health of the population. Secondly, the recommendations made to the Observatory's Board of Directors to promote the ethical management of the links of interest of the Observatory and its members, as well as sound collaboration with the agri-food industry, were presented. More specifically, the stages of a process for declaring, analysing and managing members' links of interest were detailed, and relevant questions to ask in order to guide decision-making that guarantees the preservation of the Observatory's institutional integrity when it comes to possible collaborations with the private sector were presented. In the end, it is hoped that the recommendations contained in this chapter will serve as inspiration and guidance for other public institutions which, like the Observatory, wish to ensure their institutional integrity through a transparent process of disclosure and management of COI, as well as through balanced partnerships with the private sector.

Appendix of Decision-Making Tools

Appendix 1: Tools for COI analysis and management

ANSES — Links and conflicts of interest: guide to analysing declared interests

Document description: This document is the guide for analyzing the interests declared by ANSES members. It served as inspiration for the one proposed in the section entitled "Assessment of the intensity of declared links".

Link

Overview:

Item no.	Link to declare	Declared situation	Intensity of the relationship
1.	**Main activity**		
	Main paid or unpaid activity(ies) carried out currently and over the last 5 years on a full-time or part-time basis[1]	Activity within a company or organization **likely to** benefit tangibly or be significantly penalized by the work, opinions and decisions of Anses and whose activity, techniques or products fall within the scope of Anses*.	**Major link**
		Activity within a company or organisation that is **not likely to** derive any tangible benefit or be significantly penalised by the work, opinions and decisions of Anses, but whose activity, techniques or products fall within Anses' field of competence*.	Minor link
		Activity within a company or organisation that is **not likely to** derive any tangible benefit or be significantly penalised by the work, opinions and decisions of Anses and for which neither the activity, nor the techniques nor the products fall within Anses' field of competence*.	Link out of scope
2.	**Secondary activities**		
2.1	Participation in a decision-making body of a public or private organisation whose activities, techniques or products fall within the public health and health safety remit of the organisation(s) or collegiate body(ies) covered by the declaration.[2]	Member, **with or without remuneration**, of the board of directors, supervisory board, management board or equivalent, of an organisation **likely to** derive a tangible benefit or be significantly penalised by the work, opinions and decisions of Anses*.	**Major link**
		Member, **with or without remuneration**, of the board of directors, supervisory board, management board or equivalent of a body that is **not likely to** derive any tangible benefit or to be significantly penalised by the work, opinions and decisions of Anses or that does not fall within Anses' field of competence*.	Minor link or out of scope

[1] Salaried activity(ies), self-employed activity(ies) or other (voluntary activity, retired...)

[2] This includes healthcare establishments, companies and consultancy bodies, professional bodies (learned societies, healthcare networks, CNPS) and associations, including associations of healthcare system users.

2.2	Consultancy, advisory or expert activity(ies) carried out for a public or private body falling within the public health and health safety remit of the body(ies) or collegiate body(ies) covered by the declaration.[3]	**Paid** consultancy, advisory or expert activity for a body **likely to** derive a tangible benefit or be significantly penalised by the work, opinions and decisions of Anses*.	**Major link**
		Regular, **unpaid** consultancy, advisory or expert activity for a body **likely to** derive a tangible benefit or to be clearly penalised by the work, opinions and decisions of the Anses*.	**Major link**
		Occasional, unpaid consultancy, advisory or expert activity for an organisation **likely to** derive a tangible benefit or to be significantly penalised by the work, opinions and decisions of Anses*.	Minor link
		Occasional or unpaid consultancy, advisory or expert activity for a body that is **not likely to** derive any tangible benefit or be significantly penalised by the work, opinions and decisions of Anses or that does not fall within Anses' field of competence*.	Minor link or out of scope
2.3	Participation(s) in scientific work or studies for public or private organisations within the public health and health safety remit of the organisation(s) or collegiate body(ies) covered by the declaration.	Participation in work, **with significant individual remuneration**, or provision of significant material resources, from a public or private organisation **likely to** derive a tangible benefit or be clearly penalised by the work, opinions and decisions of Anses*.	**Major link**
		Participation in work**, without individual remuneration** but with funding paid to the employer, by a public or private organisation **likely to** derive a tangible benefit or be significantly penalised by the work, opinions and decisions of the Anses*.	Minor link
		Participation in work, **with or without individual remuneration**, from a public or private body that is **not likely to** derive any tangible benefit or be significantly penalised by the work, opinions and decisions of Anses or that does not fall within Anses' field of competence*.	Minor link or out of scope
2.4		Any intervention (writing of an article, congress, conference, symposium, public meeting, training, etc.), **with individual remuneration or reimbursement of the accommodation or travel expenses of a non-participating companion** by a company or organisation **likely to** derive a tangible benefit or be clearly penalised by the work, opinions and decisions of Anses*.	**Major link**

[3] In particular, this heading covers consultancy or representation activities, participation in a working group or scientific council, auditing activities or the drafting of expert reports.

		Any **unpaid** intervention (writing of articles, congresses, conferences, symposiums, public meetings, training, etc.) **where the registration or travel costs are covered** by a company or organisation **likely to** derive a tangible benefit or be significantly penalised by the work, opinions and decisions of Anses.	Minor link
		Any intervention (writing of articles, congresses, conferences, symposiums, public meetings, training, etc.), **with or without individual remuneration or coverage of registration or travel expenses,** by a company or organisation that is **not likely to** derive any tangible benefit or be significantly penalised by the work, opinions and decisions of the Anses or that does not fall within the Anses' field of competence.	Minor link or out of scope
2.5	Invention or ownership of a patent or of a product, process or any other form of non-patented intellectual property, relating to the field of competence in the field of public health and health safety, of the body(ies) or collegiate body(ies), subject of the declaration.	Owner or inventor of a patent, product, process or any other form of non-patented intellectual property relating to a subject or theme covered by the declarant, **with or without remuneration*.**	**Major link**
		Owner or inventor of a patent, product, process or any other form of non-patented intellectual property, unrelated to a subject or theme dealt with by the declarant, **with or without remuneration**, or not falling within the field of competence of Anses*.	Minor link or out of scope
3.	**Activities you lead or have led**		
	Management of activities financed by a profit-making organisation whose corporate purpose falls within the public health and health safety remit of the organisation(s) or collegiate body(ies) covered by the declaration.[4]	Director of an entity (service, UMR, department, etc.) or project manager whose entity receives a **significant part of its resources** from one or more contracts with an organisation **likely to** benefit tangibly or be significantly penalised by the work, opinions and decisions of Anses*.	**Major link**
		Director of an entity (service, UMR, department, etc.) or project manager whose entity receives an **insignificant proportion of its resources** from one or more contracts, with an organisation **likely to** derive a tangible benefit or be significantly penalised by the contracts. work, opinions and decisions of Anses*.	Minor link
4.	**Financial holdings**		
	Financial holdings in the capital of a company whose corporate purpose falls within the public health and health safety remit	Holder of a **significant share of the capital** of a company **likely to** derive a tangible benefit or be significantly penalised by the work, opinions and decisions of Anses*.	**Major link**

[4] The type of payment may take the form of grants or contracts for studies or research, scholarships or sponsorship, payments in kind or cash, or equipment. This applies in particular to presidents, treasurers and members of boards of directors, including associations and learned societies.

	of the body(ies) or collegiate body(ies) covered by the declaration.[5]	Holder of an **insignificant share of** a company's **capital**, **likely to** derive a tangible benefit or be significantly penalised by the work, opinions and decisions of Anses*.	Minor link
5.	**Close relatives**		
	Relatives with activities or financial interests in any structure whose corporate purpose falls within the public health and health safety remit of the organisation(s) or collegiate body(ies) covered by the declaration[12].	A close relative, **employee or significant shareholder of** a company or organisation **likely to** derive a tangible benefit or be significantly penalised by the work, opinions and decisions of Anses*.	**Major link**
		A close relative, or **only a shareholder with a non-material interest**, of a company or organization **likely to** derive a tangible benefit or to be significantly penalized by the work, opinions and decisions of Anses*.	Minor link
		A close relative, **employee or significant shareholder of** a company or organisation that is **not likely to** derive any tangible benefit or be significantly penalised by the work, Anses* opinions and decisions	Minor link or out of scope
6.	**Positions and elected offices currently held**		
	Town councillor, mayor, local authority councillor, general councillor, regional councillor, member of parliament, senator.	Elected official whose mandate is likely to be directly affected by the work, opinions and decisions of the Anses*.	**Major link**
	Town councillor, mayor, local authority councillor, general councillor, regional councillor, member of parliament, senator.	Elected official whose mandate or whose local authority is not likely to be directly affected by the work, opinions and decisions of Anses*.	Minor link or out of scope
7	**Other links of which you are aware that may give rise to conflicts of interest**		
	Other links of interest	Given the potential diversity of situations reported under this heading, they are analysed on a case-by-case basis.	

Note: * The terminology used for each section of the grid is "Anses field of competence", but in the context of COI analysis, this refers to the mandate of each expert within the various collegiate bodies and, for Anses staff, to the position of each staff member.

[5] This section must be used to declare financial holdings in the form of listed or unlisted securities, whether shares, bonds or other financial assets in a company or sector concerned, one of its subsidiaries or a company in which it holds a share of the capital within the limits of your immediate and expected knowledge. You are asked to indicate the name of the establishment, company or organisation, the type of financial holding and its amount in absolute terms and as a percentage of the capital held. Any direct financial holding in the capital of a company in excess of €5,000 or 5% of the capital held must be declared. Collective investment funds such as SICAVs or FCPs — in which the individual has no control over management or composition — are excluded from the declaration.

Appendix 2

HAS — Guide to declarations of interest and management of conflicts of interest

Description of the document: This document is a complete process for disclosing, analysing and managing declarations of interest by HAS members.

Link

Overview: Part 1 establishes what constitutes a link and a conflict of interest. Part 2 explains the disclosure process. Part 3 offers a way of analysing the disclosed links of interest. This part is similar in content to what is proposed in Appendix 1, although it is in text rather than table format. Part 4 details how to manage interests deemed problematic. Part 5 describes the structure and operation of the Ethics and Independence of Expert Committees (similar in some respects to the EAC).

Appendix 3: Tools to ensure beneficial collaboration

Yves Jalbert — Proposal for a decision-making tool to help choose a partner for a project or activity related to nutrition or physical activity

Document description: This tool is designed to guide decision-making when considering collaboration with another player in the food sector. It was developed under the coordination of Yves G. Jalbert, with the support of the scientific committee of the activity *Collaborer ou non avec l'industrie agroalimentaire dans la lutte contre l'obésité?* held on 26 November 2014 as part of the Journées annuelles de santé publique.

Link

Overview:

Diagnostic et gestion d'un conflit d'intérêts
Proposition d'un outil d'aide à la prise de décision dans le choix d'un partenaire pour la réalisation d'un projet ou d'une activité en lien avec l'alimentation ou l'activité physique[1]
Collaboration recherchée
Quelle est la nature de la collaboration (financière ou non financière) proposée ou souhaitée avec le partenaire?
Quels sont les intérêts communs ou divergents au regard des buts de santé et bien-être de la population?
Profil de l'organisation
Quelle est la mission de l'organisation?
Quels sont les objectifs de santé et de bien-être de l'organisation et du projet ou activité?
Quels sont les énoncés de politiques internes en matière de conflits d'intérêts?
Profil du partenaire
Qui est le partenaire?
Quelle est la mission du partenaire?
Quels sont les énoncés de politique en matière de santé et de bien-être ou de responsabilité sociale du partenaire?
Diagnostic : Y a-t-il présence d'un conflit d'intérêts réel, potentiel ou apparent?
Un conflit d'intérêts représente un ensemble de circonstances dans lesquelles une opinion ou une action professionnelle concernant un intérêt primaire (ex.: les objectifs de santé publique de l'organisation) peut être indûment influencée par un intérêt secondaire (ex.: un intérêt commercial du partenaire). Cet intérêt secondaire peut porter atteinte, ou être raisonnablement considéré comme portant atteinte, à l'indépendance et à l'objectivité des travaux de l'organisation. Un conflit d'intérêts peut être individuel ou institutionnel et reposer sur un intérêt commercial ou financier ou tout autre intérêt. http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_6-fr.pdf?ua=1
Oui
Non
Si absence d'un conflit d'intérêts – Rédaction d'une entente formelle clarifiant les conditions d'engagement des parties
Si présence d'un conflit d'intérêts : Évaluer la portée du conflit d'intérêts
Questions pour soutenir l'évaluation du conflit d'intérêts
• Quelle est la nature du conflit d'intérêts (réelle, potentielle ou apparente)?
• Quels intérêts ou responsabilités se trouvent en conflit?
• Quels acteurs des parties sont directement impliqués dans le conflit d'intérêts?
• Les intérêts ou responsabilités sont-ils importants pour les parties impliquées?
• Des réputations ou crédibilités sont-elles menacées ou en périls?
• L'indépendance de l'organisation est-elle compromise?
• Comment le conflit d'intérêts peut-il être perçu par les gens externes à l'organisation?
• Quels sont les risques et dommages potentiels sur les objectifs de santé et bien-être de l'organisation?
• Quels autres acteurs peuvent être touchés par ces risques et dommages?
Non
Partenariat non souhaitable Revenir au début
Oui
Gestion : Peut-on gérer le conflit d'intérêts avec le partenaire?
Stratégie de la gestion du conflit
• Quelle forme d'engagement entre les parties serait la plus efficace pour l'atteinte des objectifs de santé et de bien-être de l'organisation?
• Proposition d'un plan de gestion du conflit réel, potentiel ou apparent avec le partenaire
Acceptation de collaboration du partenaire – Rédaction d'une entente formelle clarifiant les conditions d'engagement des parties
Oui
Non
Refus de collaboration du partenaire Revenir au début
[1] Cet outil a été développé sous la coordination de Monsieur Yves G. Jalbert, avec le soutien du comité scientifique de l'activité Collaborer ou non avec l'industrie agroalimentaire dans la lutte contre l'obésité? tenue le 26 novembre 2014 dans le cadre des Journées annuelles de santé publique. Toute reproduction totale ou partielle n'est permise qu'en mentionnant la source.
Institut national de santé publique Québec

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Part 3. Institutional Policies

Part 3 examines the institutional dimensions of managing COI in Canadian universities, with a focus on research integrity and policy development. A series of empirical studies and policy analyses document how universities have responded to growing public and governmental concerns about COI, particularly in the context of research funding, academic-industry partnerships, and the ethical governance of scholarly activities. Findings are presented from a comprehensive review of research misconduct and COI policies across Canadian universities and medical schools, highlighting significant variability in policy clarity, content, and implementation. Legalistic and inspirational policy approaches are contrasted, the readability and ethical robustness of existing documents are compared, and the overreliance on disclosure as a management tool is critiqued. Comparative frameworks are used to assess the strengths and limitations of Canadian institutional policies relative to international standards. Finally, a model COI policy is presented, that emphasizes principles of transparency, shared responsibility, and decentralized governance, and which is designed to be accessible (in terms of content and structure) and pertinent for all members of the university community.

Key themes include the need for clear definitions of COI, the importance of education and training, and the role of institutional culture in shaping ethical behaviour. The articles advocate for a more integrated, reflexive, and context-sensitive approach to COI policy-making, one that balances regulatory clarity with ethical deliberation in support of a culture of academic integrity.

Articles

- Research misconduct policies of Canadian universities
- Conflict of interest policies at Canadian universities: clarity and content
- Legalistic vs inspirational: comparing university conflict of interest policies
- Conflict of interest policies at Canadian universities and medical schools: some lessons from the AMSA PharmFree Scorecard
- Developing a model conflict of interest policy at the Université de Montréal

Articles

Research misconduct policies of Canadian universities

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Original version: Schoenherr J, Williams-Jones B. Research misconduct policies of Canadian universities. Canadian Journal of Higher Education. 2011;41(1):1-17.

Abstract

In a context of increasing attention to issues of scientific integrity in university research, it is important to reflect on the governance mechanisms that universities use to shape the behavior of students, researchers, and faculty. This paper presents the results of a study of 47 Canadian university research integrity/misconduct (RIM) policies: 41 institutions (87%) had distinct policies dealing with research misconduct, 37 (90%) of which took the form of research integrity/misconduct policies. For each of these 41 documents, we assessed the stated policy objectives and the existence (or not) of procedures for managing allegations of misconduct, definitions of misconduct, and sanctions. Our analysis revealed that, like their American counterparts, most Canadian universities had policies that contained the key elements relevant to protecting research integrity and managing misconduct. Yet, there was significant variability in the structure and content of these policies, particularly with regard to practical guidance for university personnel and review bodies.

Acknowledgements

The authors would like to thank Zubin Master and Gordon Lawson for helpful remarks in development of this research. Williams-Jones' research was supported by the Social Sciences and Humanities Research Council of Canada (SSHRC), the Fonds de recherche du Québec — Société et culture (FRQ-SC), and the Canadian Institutes of Health Research (CIHR).

Introduction

While not new, concerns about scientific integrity, academic misconduct, and conflicts of interest have in recent years been receiving increasing public and policy attention in the international research community. In Canada, issues of research integrity and misconduct are beginning to be addressed through discussions in policy forums, education and training programs, and the implementation of policies and committee review. Surprisingly, there is very little empirical information available about the actual policy mechanisms in place that govern the Canadian scientific community (1,2). To respond to this lacuna, in 2007-2008 we conducted a quantitative study of research integrity/misconduct (RIM)[1] policies at 47 Canadian universities, analysing a total of 41 distinct policies. As the implementation of similar policies has been addressed elsewhere (1), the policy analysis presented here aims to provide a comprehensive and descriptive assessment of the RIM policy landscape in Canada. To assess these policies, we used a grid of 12 key components — a synthesis of key components recommended by Steneck (3), CHPS Consulting (4), Greene, Durch, Horwitz, and Hopper (5), and Lind (6) — that we argue should be present in a RIM policy (see Table 3 for a complete list).

[1] As shown in Table 1, there is enormous diversity in the naming of institutional policies. Nonetheless, as most of the policy titles include the keywords "research", "integrity", and "misconduct" (see Table 2), for the sake of brevity we have chosen to refer to these policies as "research integrity/misconduct policies" or RIM policies.

There have been a number of studies in the United States documenting the range and scope of research integrity and misconduct policies implemented by academic institutions (4-6) and biomedical research facilities (7). More well examined, both in the U.S. and internationally, have been policies for the management of various types of conflicts of interest (8-11), and professional codes of ethics or codes of conduct (12-16). It is important, however, to distinguish between these other types of policies or guidelines, as well as the committees that use them, and determine whether those policies are dealing with research integrity or scientific misconduct. Codes of ethics tend to constitute some admixture of inspirational, regulatory, and educational elements (17); conflict of interest policies are directed toward more general concerns regarding the avoidance of real or potential bias; and policies on research ethics are by and large restricted to ensuring the protection of human (or animal) research participants. For instance, while policies governing research ethics and research ethics boards (REBs) are concerned with some issues related to research misconduct (i.e., if confidentiality is not maintained or research subjects are exposed to unacceptable risk of harm) they may not have the necessary procedures or guidelines for dealing with the more general norms of science (e.g., duplicate publications or data fabrication).

While the issues dealt with by RIM policies may overlap to some extent with these other documents (e.g., codes of ethics, conflict of interest policies, research ethics guidelines), RIM polices differ in important ways with regard to scope, mandate, and punitive powers. Designed to address the full range of activities conducted throughout the research process, we argue that RIM policies should constitute a distinct class of regulatory policy and one worthy of focused and detailed analysis. Our study contributes to such an analysis by presenting the current state of Canadian RIM policies, and also reflecting on some of the strengths and limitations of these documents.

The University Policy Landscape

Before proceeding to our study of the Canadian university policy environment, it will be helpful to first briefly review the existing academic literature on policies governing research integrity and misconduct. This will set the groundwork for explaining our choice of methodology and provide justification of our selection of key components that should be included in RIM policies.

US Institutional Policies

Institutional policies that address research integrity have not been the subject of much empirical examination. Those studies that have assessed university and other institutional policies have generally sampled large and diverse population sets in the United States (e.g., universities, research centres, hospitals), used a variety of methods, and evaluated different criteria, thus making direct comparisons between these studies difficult. Nonetheless, three studies are worth particular attention, notably those of Greene et al. (5), CHPS Consulting (4), and Lind (6).

Greene and colleagues (5) conducted the first and most extensive review — using an open-ended questionnaire that analysed both formal written and informal unwritten policies — to study 493 policies of academic institutions and hospitals in the U.S. Of the written policies, only 33% explicitly mentioned “research fraud” with another 38% containing such provisions in broader policies. Written policies were broken down into seven procedural phases, variously represented as informal resolutions (27%), discussions (29%), investigations (69%), arbitration/mediations (18%), hearings (44%), appeals (35%), and sanctions (56% explicitly specified, 16% left unspecified). This study also identified eight additional policy

considerations: the importance of defining research fraud, the need to distribute policies or guidelines to the university community, the inclusion of participants (e.g., accuser and accused) in procedures, the notification of funders and journals, publicity and transparency of procedures, attention to legal and quasi-legal considerations, the power of deterrence, and the importance of peer review. Among their key findings, Greene et al. noted widespread differences both in the degree and extent to which policies covered issues of research misconduct.

The CHPS Consulting review (4), prepared for the U.S. Office of Research Integrity (ORI) at the Department of Health and Human Services, examined institutional policies in a different manner. Their sample population of 156 university, hospital, and research centre policies had already been selected by the ORI as conforming to existing federal regulations concerning research integrity. The study examined more specific issues than those examined by Greene et al (5). Six topical areas were identified (from an initial list of eighteen): definition of misconduct, allegation procedures, fairness of investigation process, rights of parties involved, inquiry and investigation processes, and other considerations. All of these elements were represented to varying degrees in the institutional policies examined. For instance, inclusion of specific policy elements ranged from unanimous coverage, such as the specification of committee membership and rights of respondents (100%), only slight majority representation such as specification of sanctions (73%), appeal processes (56%), and definitions of misconduct (53%), to a minority of policies (41%) including confidentiality provisions.

Lastly, although Lind's (6) review examined only 41 U.S. universities, this more recent study nonetheless presented similar findings. The twenty areas that Lind examined were grouped into five categories containing preliminary components (41%; e.g., misconduct definition, mentoring), ensuring fairness (54%), respondent-whistleblower rights (71%), inquiry and investigation (78%), and outcomes (53%). Not all institutional policies contained all possible topic areas, although the majority of elements were touched on by most policies.

While there may be a lack of consensus in the literature with regard to the necessary and sufficient components of institutional RIM policies, it is clear that there are a number of widely agreed upon key elements. Steneck (3), in his examination of the history of institutional policies (cf. 18), identified these basic features or elements. Specifically, he lists the considerations for creating an effective RIM policy as including definitions of misconduct, inquiries/allegations assessment, and investigation/adjudication. This list is thus arguably a minimal standard for institutional policies. A more comprehensive analysis should, we suggest, consider both these general elements as well as more precise subcomponents that would enable RIM policies to be operationalized.

Canadian Institutional Policies

Pencharz (2) conducted the first review of Canadian university RIM policies. His report was a high-level analysis developed to examine whether the standards of Memorial University of Newfoundland (henceforth referred to as Memorial University) were comparable to other universities and whether their policy met national standards, namely those set out in the *Tri-Council Policy Statement: Integrity in Research and Scholarship* (TCPS-IRS, 1994, updated 2005) (19).[2] After reviewing a selection of policies from six Canadian universities, and other

[2] As a condition of receiving funding from the three main federal granting councils in Canada (the Social Science and Humanities Research Council, SSHRC; the Canadian Institute of Health Research, CIHR; and the Natural Science and

scholarly references addressing standards and guidelines, Pencharz concluded that Memorial University's policy was sufficient and was applied satisfactorily in the specific case of Dr. Ranjit Chandra, who had falsified numerous studies over the course of nearly three decades as a professor at the University. Though insightful, the Pencharz study is limited in two respects. First, due to the small sample size, the study cannot be said to fully address the diversity of concerns regarding RIM policies at Canadian universities. Second, as the Pencharz study was not designed to quantitatively assess specific policy elements, there is no means by which to compare one university to another. A more comprehensive assessment is required.

More recently, a report commissioned by the Canadian Research Integrity Forum (CRIF)[3] examined a broader cross-section of institutions and policies (1) than the study by Pencharz (2). Thirty-seven policies were examined with the majority (27) selected from universities. The results were based on both qualitative and quantitative methods consisting of policy analysis and interviews with academic administrators, respectively. Despite many similarities with the findings of our study (examined further in the Discussion section) there are several noteworthy differences. First, the HAL (1) report did not quantify either the extent to which stakeholders (e.g., faculty, external affiliates, students) or components of the allegation procedure (i.e., reporting, initial inquiry, and formal investigation) were included in institutional policies. Second, there was differential representation of types of misconduct observed in the HAL review and our study that is likely attributable to the sample populations. Finally, the number of universities sampled in the HAL review was smaller — 27 in comparison with the initial set of 47 (41 policies analysed) in our study — potentially skewing results and providing an incomplete picture of the university policy environment. Our study thus aims to provide a more comprehensive survey of the Canadian policy landscape than has been achieved in previous studies.

Method

In order to select an appropriate sample population for our study of Canadian university research integrity policies, we used a measure that considered both university productivity and research funding received as a means of accounting for the impact of an institution on the scientific record. Arguably, those institutions that have the greatest impact should also have effective policies for ensuring the integrity of their scientific community. After examining potential populations, an initial set of the 50 highest ranked universities was identified using the 2008 annual report published by RE$EARCH Infosource. The composite indicator used in that report considers the annual rate of publication and funding received by the institution and faculty members. In order to limit the study size, the sample was

Engineering Research Council, NSERC) — collectively referred to as the Tri-Council — university researchers must comply with general principles of responsible scientific practices. These principles include appropriate acknowledgement of the contributions of others (including authorship), revealing potential conflicts of interest, and maintaining rigour throughout the research and reporting process. Institutional responsibilities included in the TCPS-IRS require the promotion of research integrity, the investigation of allegations of misconduct, and reporting on the investigation outcomes to the appropriate council.

[3] Established in 2006, the CRIF, formerly the Canadian Research Integrity Committee, is a non-partisan group with seventeen members representing governmental and non-governmental organizations from across Canada; notably, it includes members from the three federal granting councils (SSHRC, NSERC, CIHR) and 2 national university associations (AUCC, CAUT) (20).

restricted to full-service institutions (i.e., those institutions with undergraduate and graduate programs, medical and business schools, etc.), with a result of 47 institutions (Table 1).[4]

Table 1: Canadian Institutional Policies (n=47)

Institutions	**Policy Title**
Acadia University	Research Integrity Policy
University of Alberta	Research and Scholarship Integrity Policy
University of British Columbia	Scholarly Integrity
Brock University	Policy on Integrity in Research Scholarship
Carleton University	NA
University of Calgary	Integrity in Scholarly Activity
Cape Breton University	NA
Concordia University	Guidelines for Ethical Action
Dalhousie University	Policy on Integrity in Scholarly Activity
University of Guelph	Academic and Fraud Misconduct
Lakehead University	Guidelines and Policy for the Ethical Conduct of Research and Procedures for Investigating Misconduct
Laurentian University	Policy on Integrity in Research and Scholarship
Université Laval	Politique relative à l'intégrité scientifique
University of Lethbridge	Integrity in Research and Scholarship
University of Manitoba	Procedures for Investigating and Reporting Academic Fraud
McGill University	Procedures for Investigating Reports of Misconduct in Research
McMaster University	Procedures for Inquiries and Hearings regarding Allegations of Misconduct in Research for Faculty, Staff and Post-Doctoral Fellows
Memorial University	Policy Statement on Integrity in Scholarly Research
Université de Moncton	Politique d'intégrité en recherche
Université de Montréal	Probité intellectuelle en recherche
University of New Brunswick	NA
University of Northern British Columbia	General Research Ethics
University of Ottawa	Guidelines for the Ethical Conduct of Research and Procedures for Investigating Misconduct
University of Prince Edward Island	Policy on Integrity in Research and Scholarly Work
Université de Québec à Abitibi-Témiscamingue	Politique d'intégrité dans la rechereche et les travaux d'érudition
Université de Québec à Chicoutimi	Procedure relative a l'inconduite dans les travaux de recherche ou de creation, Procédure relative au traitment des plaintes concernant l'inconduite
Université de Québec à Montréal	Politique sur les conflits d'intérêts et sur l'intégrité académique
Université de Québec à Rimouski	Politique institutionnelle en matière d'intégrité scientifique
Université de Québec à Trois-Rivère	Politique d'éthique en recherche
Queen's University	NA
University of Regina	Procedure for Reporting and Investigating Scholarly Misconduct, Misconduct Policy
Royal Military College of Canada	Misconduct in Research
Ryerson University	NA
St. Francis Xavier	NA
St. Mary's University	Policy Statement on Integrity in Research and Scholarship and Procedures for Reporting and Investigating Scholarly Misconduct

[4] During the first phase of our study, this sample constituted 46 universities. However, during the write-up of these results an additional report was published on the top 50 universities including one additional university that was added to the sample population. Not all institutions were classified as "full-service" thus reducing the sample population from 50 to 47.

University of Saskatchewan	Policy Dealing with Misconduct in Scholarly Work
Université Sherbrooke	Politique, règles et procédures sur l'intégrité en recherche et sur les conflits d'intérêts
Simon Fraser University	Integrity in Research and Misconduct in Research
University of Toronto	Framework to Address Allegations of Research Misconduct
Trent University	Policy on Scholarly Misconduct
University of Victoria	Policy on Scholarly Integrity
University of Waterloo	Integrity in Research, Administrative Guidelines
University of Western Ontario	Policy and Procedures for the Conduct of Research
Windsor University	Ethical Conduct of Research
Wilfrid Laurier University	Fraud and Misconduct in Academic Research and Scholarly Activity
University of Winnipeg	Policy and Procedures on Integrity in Research and Scholarship
York University	Misconduct in Academic Research

Between April 2007 and July 2008, general Internet and individual website searches were conducted to obtain the university policies. If a policy could not be retrieved via an Internet search, the university's research office was contacted by phone or email to request relevant documentation. In order to clarify certain areas of French-language policies, two translation engines were used to verify policy content (Google Translate, Babelfish). Both translation engines returned results conforming to the authors' interpretation of the policy. This method also proved useful for the keyword analysis mentioned below. Where there may be an imperfect translation, French words are presented in parentheses.

To ensure the clarity of our results, only an institution's key or central RIM policy was reviewed; policies of individual units, departments, faculties, colleges, or schools were excluded. Where a single policy document was not immediately available, other related policies were examined to ensure that relevant information was not contained elsewhere. To this end, the documents surveyed included the following terms in their title: *honesty*, *integrity (integrité* and *probité)*, *misconduct (inconduite)*, *fraud*, *research*, *science*, *intellectual*, *scholarly*, *academic*, and *ethics* (see Table 2). When any combination of these terms was contained in the document title, the document was examined. As a result, both central research integrity measures as well as distributed policies can be considered together. Additionally, although some policy elements are potentially related to research integrity and mentioned in separate documents (e.g., collective agreements may contain sanctions and appeal procedures), unless these are specified in the context of research integrity or misconduct, they were not included in our analysis.

The goal of our study was to identify a policy's underlying purpose, the rights of the parties involved, the perceived nature of integrity and misconduct, and the procedures used in the course of dealing with allegations of misconduct. Using the basic elements identified by Steneck (3) as a starting point — that is, misconduct definitions, inquiries/allegations assessment, and investigation/adjudication — we included additional policy elements or components identified in the three studies mentioned above (4-6). This produced a total of 12 components (and numerous sub-components) for our analysis: 1) Existence of a RIM Policy, 2) Objectives of Document, 3) Applicability Statement, 4) Responsible Scientific Practices, 5) Roles and Responsibilities, 6) Definition of Misconduct, 7) Allegation Submission Procedure, 8) Rights of the Parties, 9) Inquiry, 10) Investigation, 11) Follow-Up Procedures, and 12) Other (see Table 3).

The coding of the data was conservative: when an item was clearly evident or could be reasonably inferred it was counted as present and given a score of one; if there was a

possibility that an item was present but was not clearly evident it was given a null score. For example, if a document mentions that an inquiry results in a report, or that a committee's conclusions are to be communicated to an appropriate official, it was counted as a report. If instead it was stated that an investigator recommended further investigation but did not mention a summary of available evidence, it was not counted, as the implications of such statements are not clear.

For the purpose of clarity, some terminological notes are required. Unless otherwise specified, *Dean* refers to the dean of the faculty of the respondent; *President* refers to the president of the university; *Vice-Presidents* are specified as they include those designated for *Research*, *Graduate Studies*, *Academic*, and *International*; and *University* refers to the academic institution under consideration. The term *granting councils* refers to the three Federal or Tri-Council funding agencies (SSHRC, CIHR, and NSERC). This latter term can be distinguished from *funders* who represent any party external to the university that provides funds for research (including, for example, charitable organizations, provincial governments or agencies). Lastly, a *third party* typically refers to a representative of the collective bargaining unit. However, some policies leave this open to interpretation and it potentially includes a senior member of the faculty, or a legal representative.

Results

From an initial set of 47 Canadian universities, we identified 41 unique policy documents, 37 (90.2%) of which were in the form of distinct RIM policies (it should be noted that since the time of this survey, several institutions have adopted or modified their policies). This preference suggests recognition of the need for a self-contained set of procedures to address the specific issues of research integrity and misconduct. In contrast, only three (7.3%) documents were located in collective agreements and one (2.4%) in the form of a research ethics document. This latter document could also be considered a distinct RIM policy that simply adopted different terminology. This difference in observed titles prompted an analysis of keywords used to describe research misconduct policies. A cursory examination of title keywords was performed as a means of checking that appropriate documents had been obtained. The keywords also demonstrate how universities conceptualize the issue of research integrity and misconduct. Table 2 shows the percentage of policy documents with a given keyword with frequencies in parenthesis.

Table 2: Keyword Analysis

Keyword	**Percentage (Frequency)**
Research	**65.8**% (25)
Integrity (Probité/Intégrité)	**54.1**% (20)
Scholarship	**39.5**% (15)
Misconduct (Inconduite)	**32.4**% (12)
Ethical	**13.5**% (5)
Academic	**10.5**% (4)
Conduct	**5.4**% (2)
Scientific	**5.4**% (2)
Fraud	**2.7**% (1)

The analysis of keyword usage in policy titles indicates that the majority of documents pertain to “research” (65.8%) and “integrity” (54.1%), while slightly fewer are concerned with “scholarship” (39.5%) and “misconduct” (32.4%). Interestingly, far fewer documents used the keywords “ethics” (13.5%) and “academic” (10.5%) in their titles. The most infrequent terms included “conduct” (5.4%), “scientific” (5.4%), and “fraud” (2.7%). On average, 2.4 keywords were used in a document title, with a range of 1 to 5 keywords.

In our study, the main components or elements of interest for a university policy were grouped topically for analysis, and then further broken down into subcomponents. Where a primary component was absent, subcomponents were excluded so as not to bias scoring through double counting. Table 3 presents a summary of these findings and is followed by a discussion of the results for each main component included in university policies.

Table 3: Inclusion of Main Components in Canadian University Policies

Policy Components	No. of Policies	% of Policies
(1) Research Integrity/Misconduct Policy	41/47	87.2
(2) Objectives of Document	38/41	92.7
(i) Tri-Council or Individual Agency	19/38	50.0
(ii) Other Funders	12/38	31.6
(iii) Legal Requirements	11/38	28.9
(3) Applicability Statement	41/41	100.0
(i) Staff/Faculty	41/41	100.0
(ii) Student	29/41	70.7
(iii) External Affiliates	30/41	73.2
(4) Responsible Scientific Practices	32/41	78.0
(i) Data Management	25/32	78.1
(ii) Conflict of Interest	15/32	46.9
(iii) Authorship Guidelines	17/32	53.1
(5) Roles and Responsibilities	28/41	68.3
(i) Researchers	26/28	92.9
(ii) Institution	19/28	67.9
(iii) Academic Administration	21/28	75.0
(6) Definition of Misconduct	38/41	92.7
(i) Fabrication and Falsification	38/38	100.0
(ii) Plagiarism	38/38	100.0
(iii) Conflicts of Interest	29/38	76.3
(iv) Misuse of Funds	25/38	65.8
(v) Authorship Inclusion/Exclusion	22/38	57.9
(vi) Violations of Research Ethics	22/38	57.9
(vii) Failure to Follow Fed. Regulations	22/38	57.9
(viii) Other Misconduct	33/38	86.8
(7) Allegation Submission Procedure	38/41	92.7
(i) Require Written Submission	32/38	84.2
(ii) Require Signature	18/38	47.4
(iii) Identification of the Complainant	16/38	42.1
(iv) Allowance for Anon. Complaints	6/38	15.8
(v) Identification of the Respondent	13/38	34.2
(vi) Inclusion of All Relevant Details	20/38	52.6
(8) Rights of the Parties	37/41	90.2
(i) Confidentiality of Parties	34/37	91.9
(ii) Rights of Complainants	26/37	70.3

(iii) Rights of Respondents	30/37	81.1
(9a) Preliminary Inquiry Committee	34/41	82.9
(i) Initial Inquiry Performed by Dean/VP	28/34	82.4
(ii) Members External to Department	12/34	35.3
(iii) Members Internal to Department	11/34	32.4
(iv) Members External to University	10/34	29.4
(v) Permanent Appointments	29/34	85.3
(vi) Ad-hoc Appointments	13/34	38.2
(9b) Inquiry Process	32/41	78.0
(i) Full Power of Investigation	31/32	96.9
(ii) Report Submission Required	17/32	53.1
(10a) Investigation Committee	38/41	92.7
(i) Dean or Vice-President as Primary Investigator	15/38	39.5
(ii) Members External to Department	26/38	68.4
(iii) Members Internal to Department	21/38	55.3
(iv) Members External to University	17/38	44.7
(v) Permanent Appointments	16/38	42.1
(vi) Ad-hoc Appointments	29/38	76.3
(10b) Investigation Process	38/41	92.7
(i) Full Power of Investigation	35/38	92.1
(ii) Restricted Investigation Powers	1/38	2.6
(iii) Power to Sanction	14/38	36.8
(iv) Written Report	35/38	92.1
(11) Follow-Up Procedures	31/41	75.6
(i) Appeal Mechanism	18/31	58.1
(ii) Contact Research Sponsor	25/31	80.6
(12) Other	38/41	92.7
(i) Timeline for Inquiry Process	35/38	92.1
(ii) Alignment with Collective Agreement	28/38	73.7

For Component 1, the percentage prevalence of institutional Research Integrity/Misconduct Policies is calculated for n=47 (total number of policies); for Components 2 through 12, percentages are based on n=41 (the number of policies examined); for sub-components, percentages are calculated from the nominator of the main Component.

1) Prevalence of Research Misconduct Policies

The primary purpose of this study was to identify the prevalence of research misconduct policies and their constituents. Of the 47 institutions surveyed, 41 (87.2%) had unique RIM policies that met or exceeded the TCPS-IRS (19) standards and were applicable to the university as a whole and not simply confined to specific faculties or units. This high prevalence of distinct policies indicates the clear importance that institutions are giving — at least in principle — to preventing or managing research misconduct.

2) Document Stated Objectives

Those policies that stated their objectives (92.7%) showed great disparities in terms of whether they aligned themselves with the Tri-Council policy explicitly (50%; e.g., “This policy should be read in conjunction with the Tri-Council Policy Statement on Integrity in Research and Scholarship…”), whether they mentioned funders generally (31.6%), or whether they cited the law as an impetus for the current document (28.9%). These items appeared in many different combinations and forms. Given the changing policy context regarding research integrity, research ethics, and academic integrity in Canada — e.g., there

is significant public and policy discourse about conflicts of interest (particularly in government) — it may be that stated policy objectives will change over the next few years.

3) Applicability Statement

An applicability statement refers to the portion of the text that indicates the parties who are bound by the document. For instance, one applicability statement might restrict a policy to only researchers (e.g., "These procedures apply to…any person holding an appointment governed by the University Procedures for Appointment, Promotion and Dismissal, and also apply with such variations as are necessary to complaints against persons holding Post-Doctoral Fellowships or their equivalent") whereas another might have a broad application to anyone in the university community, including students (e.g., "This Code is designed…to guide all University members (members of the Board of Governors, administrators, staff, faculty, and students)…"). A policy that is limited in scope will result in fewer cases being identified as it applies to fewer individuals. All 41 documents in our study contained applicability statements, and in all cases, they mentioned that the policy governed faculty/researcher conduct. Affiliated members of the university were generally covered under the policy (e.g., post-doctoral fellows, contractors; 73.2%), as were students (70.7%).

4) Responsible Scientific Practices

The majority of policies (78.0%) mention some items that can be counted as a facet of responsible scientific practices (e.g., "rigorous attention to citing the contributions of others…careful planning of research protocols, ensuring that methods of analysis are appropriate and assuring access to the data for a reasonable period of time…proper use of all research resources…"). Items that covered responsible scientific practices included standards for data management (78.1%), conflicts of interest (46.9%), and authorship (53.1%). In these data we see the importance of providing examples (alongside formal definitions, see Section 6 below) of what are considered responsible and irresponsible practices. Attention, however, needs to be given to the tone and language used to describe these practices (e.g., positive and "inspirational" or negative and "legalistic") as this can have an impact on the "readability" or interpretation of the document in question (11,21).

5) Roles and Responsibilities

Although most policies did not contain any substantive provision for education or training of researchers or students, a substantial number discussed the roles and responsibilities of members of the university community (68.3%). However, in some instances there was explicit mention of the duties of a supervisor to impart information to students (i.e., mentoring). Of those policies that addressed responsibilities of members of the university community, the majority mentioned the obligations of researchers (92.9%); slightly fewer indicated the duties of the academic administration such as deans, vice-presidents, etc. (75%; e.g., "The President shall decide whether the circumstances warrant an investigation.… [This] authority hereunder may be delegated"), while still fewer outlined the general role of the institution in maintaining research integrity (67.9%; e.g., "[The University] acknowledges and accepts responsibility for maintaining high ethical standards in research and scholarship, and agrees to investigate and resolve promptly and fairly all instances of alleged misconduct"). In the latter case, these policies recommended the creation of educational measures, to be conducted either annually or in the form of punctual courses. While important, such a focus on education and the responsibility of researchers may undermine (or at least minimize) the essential role to be played by institutions in promoting environments that encourage research integrity, such as through the

implementation of mechanisms that support researcher independence and prevent institutional conflicts of interest.

6) Definitions of Misconduct

Although misconduct can generally be inferred from statements on responsible scientific practices, clearly defining what constitutes unacceptable behaviour arguably provides a standard for both researchers (in a sense, part of a code of ethics), administrators, and those who are required to mediate allegations of misconduct. Moreover, making clear an institution's vision of what counts as misconduct allows this view to be challenged and debated openly by the academic community, thereby increasing transparency.

Nearly all (92.7%) institutions in our study defined misconduct in their policy. Those that did uniformly included in their definitions the fabrication and falsification of data, and plagiarism (100%), and generally also included conflicts of interest (76.3%). Importantly, though, the policies we examined rarely restricted themselves to only these issues. Other issues most commonly included in definitions of misconduct were the misuse of funds (65.8%), unauthorized inclusion or purposeful exclusion of authors from publications (57.9%), violations of research ethics norms (57.9%), and failure to meet government regulations (57.9%). Interestingly, most definitions (86.8%) also included some other form of misconduct, such as abuses of authority, misappropriation of data, gross negligence, and exclusion of honest errors. Honest errors include typographic errors that misrepresent or change the interpretations of a study's findings, errors in figures and tables presenting data, and similar unintentional mistakes. This diversity in how institutions define "misconduct" is arguably linked to the current vagueness in the broader academic community about what constitutes research integrity and good conduct. It may not be necessary for Canadian institutions to agree on a uniform or national definition of misconduct; there is arguably a place for regional and local specificity. Nonetheless, we suggest that a national discussion about what constitutes research misconduct — as well as responsible scientific practices or integrity — across the full range of academic disciplines would be of enormous help to institutional policy makers and the Canadian academic community more generally.

7) Allegation Submission Procedures

Nearly all policies (92.7%) included procedures for reporting misconduct allegations. Including such procedures within a policy document provides complainants a contact point and allows them to understand what is required of them. Allegations of misconduct are generally submitted in writing (84.2%), and in some instances, it appears that the official that allegations are reported to can assist in drafting a formal complaint. Policies differ in certain features, for example, with 47.4% requiring a signature and 42.1% requiring the identification of the complainant. Only 34.2% of policies specify the identification of the respondent as a requirement; while this may appear odd, it seems likely that the need for full identification is to be inferred when, for example, policies stipulate that all relevant details should be required when reporting the allegation (52.6%). Interestingly, very few institutions accepted anonymous allegations of misconduct (15.8%). This may be reasonable given the seriousness of such allegations (e.g., for professional and institutional reputations) and the need for due process. But given the presence of power relations that may mitigate against substantive accusations (e.g., senior vs. junior colleagues, professor vs. student), it is also necessary to have other complaint mechanisms in place, such as an Ombudsman office.

8) Rights of the Parties Involved

A critical aspect of a RIM policy is having a clearly delineated set of rights for the parties involved. In order to be succinct, these have been categorized as those of the respondent (accused), those of the complainant (accuser), and all parties with regard to the issue of confidentiality. Confidentiality was restricted to preserving the identity of the complainant and respondent from being revealed to the broader university community. Of the 37 policies that mentioned rights, most addressed issues of confidentiality of all parties involved (91.9%), while attention to the rights of complainants (70.3%) and respondents (81.1%) was roughly equivalent. Although, in general, policies stated that both complainants and respondents had the right to sit in on the proceedings of the inquiry or investigation, or to view the evidence if the proceedings were closed, respondents sometimes had the additional right to a third-party representative whereas complainants had provisions to allow for protection from reprisal. When available, these latter rights of the respective parties were rarely stated in any great detail.

9) Preliminary Inquiry Process

The preliminary inquiry stage is a vital phase in pursuing allegations of misconduct. An initial assessment determines whether a complainant's claims are substantiated and whether a subsequent investigation is required. The composition of inquiry committees was provided for in 82.9% of university policies. Most of these policies placed direct responsibility for the inquiry process on the Dean, Vice-President, or other comparable university official (82.4%); however, there is often mention that this role can be delegated if necessary. In most cases in which senior university officials are responsible for the process, the Vice-President (Research) handles the case unless there is a conflict of interest, in which case the Vice-President (Academic) is the primary contact point.[5]

Policies often require that additional individuals be involved in the initial inquiry. These individuals are sometimes external to the department (35.3%), drawn from faculty members of the department where the allegation is made (32.4%), or from outside the university (29.4%). These parties were included in various combinations to form committees. The vast majority (85.3%) of policies stated that individuals that investigate misconduct are to be permanent or term appointees to a committee, assigned for a given period of time (often a few years); only 38.2% of policies included provisions for ad hoc appointments to committees. The Dean, Vice-President, etc. make these latter appointments in accordance with guidelines that generally make explicit the need to avoid conflicts of interest. Those policies that outline committee membership criteria allow both the complainant and the respondent to object to committee selection on the grounds that these individuals could be biased. This generally results in a three-person committee being formed.

Most policies outlined the inquiry process (78%), and of these, 96.9% vested full investigatory power in the committee, allowing the examination of all available sources of information, including interviews with relevant parties and examination of original data and materials. Interestingly, only about half (53.1%) of these policies mention the submission of a written report by the inquiry committee. Reports were to be destroyed if allegations were not borne out; in those cases where no report was called for, investigators are required to indicate the need for further investigation to an appropriate official.

[5] Alternatively, many institutions place primary responsibility with the Dean, with a VP (Research or Academic) as the reserve contact. The title of the individual identified necessarily depends on the structure of the institution.

10) Investigation Process

As with the inquiry committee, the majority of institutions outlined the membership of the investigation committee (92.7%). Of these, the majority required committee members from outside the department(s) of the respondent and complainant (68.4%), with a significant number of institutions allowing for the involvement of faculty from within the department where the allegation was set forth (55.3%), but less than half allowing the involvement of experts external to the university (44.7%). This acceptance of participation by department members and rejection of external experts (probably to avoid publicity) should raise serious concerns about conflicts of interest and the objectivity of investigations. Although those within a department may be the most familiar with the research under investigation, we must also consider the fact that the academic environment is extremely competitive, and this can on occasion lead to unseemly behaviour between colleagues (even to the point of professional vendettas). As such, we strongly believe that — given their quasi-judicial nature — investigating committees be constituted by members free from real or apparent conflicts of interest.

Often the Dean or Vice-President is involved in these proceedings as the primary investigator or as chair of the committee (39.5%). Consequently, most investigations involved ad hoc groups or persons selected to conduct the investigation (76.3%) with a much smaller number of policies requiring the involvement of permanent or term appointees (42.1%). In a similar fashion to the inquiry process, a three-person committee is generally preferred.

Details on the investigation process were equally well presented in institutional policies (92.7%). In the majority of cases, committees were granted full power of investigation (92.1%), with only a very few having restricted capacities (2.6%). These restrictions generally stated that the committee was required to investigate only the charges set forth by the allegation or the findings of the inquiry stage. Presumably, for the purposes of due diligence, the committee would be able to go beyond these limits, but such statements were rarely made explicit.

Committees were also limited in terms of whether they were capable of suggesting sanctions (36.8%). The majority of committees were required to submit a written report upon completion of their investigation (92.1%). When charges were supported, these reports were retained for periods from one to ten years depending on the institution. Sanctions were imposed either by recommendation of the committee, by the Vice-President, or were spelled out in the collective agreement. If the respondent was acquitted, these reports were destroyed in a timely fashion (either immediately or within a year of the investigation).

11) Follow-Up Procedures

Follow-up procedures were also contained within the majority of institutional policies (75.6%). More than half of these policies (58.1%) mentioned some process of appeal, and were described as distinct mechanisms, or in reference to a collective agreement. A complementary provision was also evident, and most policies stipulated that after the conclusion of the investigation, any reputational harm that occurred and was unjustified, would be rectified. This includes whistleblower protection which is explicitly stated in most documents but generally not spelled out. Given the seriousness of even alleged misconduct and the difficulty of redressing tarnished reputations, it is unfortunate the more policies do not pay explicit attention to how to address this issue (besides ensuring confidentiality in the investigation process). Importantly, 80.6% of documents with follow-up procedures (that is, 31 policies) stipulated that research sponsors must be contacted at some stage during

assessment process. Few documents specified the need to contact affected parties other than funders about a judgment (e.g., journals, colleagues), nor was there consistency or agreement about at what stage of the process funders were to be notified.

12) Other items

The majority of policies also contained pertinent policy items that were outside the major categories listed above (92.7%). In general, these included specific timelines within which the various stages of the allegation, inquiry and investigation procedures should be completed (92.1%). Inclusion of such standards is important for ensuring due process and timely judgements. Where timelines cannot be met, policies required notification of the involved parties that included a justification for the delay. A considerable number of policies (73.7%) were aligned with the collective agreement between the institution and its employees, with the policy acting as a complement. In cases where they conflict, the policies state that the collective agreement takes precedence.

Discussion

Our study examined 41 research integrity/misconduct policies at Canadian universities (from an initial set of 47 universities) by breaking policies into their constituent components or elements. Although this analysis is essentially descriptive in nature, several conclusions can still be drawn concerning the foci of policy coverage at Canadian research universities, and their relationship to more general Canadian and U.S. institutional integrity guidelines.

Current Standards used in Canadian University Policies

At the most basic level, the RIM policies at Canadian universities include the essential policy components discussed by Steneck (3) and outlined in the TCPS-IRS (19). Misconduct definitions, assessment of inquiries and allegations, and investigation/adjudication procedures are all covered by the vast majority of policies. Beyond this minimal standard, it is also apparent that most policies adopted a fairly inclusive approach to dealing with the subject of research integrity in terms of the criteria used in our analysis. Policies typically laid out step-by-step procedures for dealing with misconduct, and itemized lists of basic considerations regarding research integrity. Such an approach is important both for the purposes of clarity for the parties involved in a dispute, as well as for promoting transparency of the system to the academic community and the general public.

However, as mentioned above, the extent to which these elements were dealt with (e.g., in terms of specifying the details of particular procedures) showed significant variation. Some universities only addressed a portion of the main areas recommended for policy coverage. Areas such as roles and responsibilities of members of the academic community, or responsible scientific practice, were the least covered. Although these subjects still enjoyed a strong representation across all policies, it is surprising that they were not better represented given the terms favoured by the keyword analysis (*research* and *integrity*) and the TCPS-IRS requirements for such measures. Instead, there is a clear focus on detailing procedures for addressing allegations of misconduct, and far less attention on encouraging the promotion of research integrity. Although this may simply be an artefact of the keywords used to identify the documents under consideration, the reasons for the adoption of such terminology remain intriguing and have important implications for the perception of research integrity within the scientific community.

Although it can be stated with certainty that the major procedural issues have been addressed in the majority of the Canadian policies we surveyed, there is clearly no uniform or coherent

treatment of all research integrity issues. Supporting this conclusion is the great variability in the inclusion of the (important) policy sub-components. Notably, there was very little coverage in the policies of legal matters, issues of conflict of interest, initial inquiry reports, appeal processes, or the committee's power to sanction and the sanctions available. It is important to note that some of these elements are likely covered more fully by other university polices and guidelines, for example, in conflict of interest policies and collective agreements (11,21). But if this is the case, it would seem critical to clarify and be explicit about the relationship between the central RIM policy, and other related policies and guidelines. Like Steneck (3), we must consider that the appropriateness of a policy can only be determined by considering the institutional context: each university system must be assessed as a whole to ascertain whether it is the optimal solution. It seems likely, however, that certain configurations of policies and subcomponents may provide a more transparent and effective infrastructure. Whether this is the case or not remains an empirical question.

Finally, as noted above, the present analysis is limited in that it only examines RIM policies but not their implementation. In the absence of an external body that can receive allegations, institutional policies and procedures must function autonomously. Consequently, further studies are need in order to assess the efficacy and fairness of these policies. In terms of policy efficacy, both the rate of misconduct and the estimated effectiveness of the policy infrastructure at detecting occurrences within an institution need to be considered. Of equal importance is the extent to which a policy treats equally the rights of respondent and complainant regardless of their position within the academic community. Moreover, follow-up procedures must include provisions that ensure that affected parties (e.g., journals and funders) are contacted. Although the prevalence of these components in the present study was moderately high, there is no assurance that the scientific record would be corrected in all cases.

Comparability to Other Studies

In addition to areas of policy coverage, conclusions can be drawn from a comparison with the other studies mentioned at the beginning of this paper. Although not contemporaneous, and conducted with a different methodology, the findings of the present study can be contrasted positively with the findings of Greene et al. (5), CHPS (4), and Lind (6). Specifically, in almost every area of policy coverage, the Canadian policies we reviewed are in a better state than was the case in the U.S. in the mid-1980s. This is not surprising given that it was during the 1970s and 1980s that research misconduct became a prominent concern in the U.S. and Canada (3,18). So while the Canadian research community may only be beginning to regard research misconduct as a serious problem, it has a well-developed policy infrastructure in place to address these issues, something that has undoubtedly been influenced by developments in the U.S. It should be noted, however, that our study of Canadian university policies was limited to leading research universities, whereas the Greene et al. (5) study examined the broader U.S. research community and included research centres and hospitals. Perhaps more importantly, we have shown in our study that the key areas covered by Canadian academic institutions are comparable to those within the current U.S. institutional system, as demonstrated by the CHPS (4) and Lind (6) studies. These include policy objectives, applicability statements, discussion of responsible scientific practices, definitions of misconduct, rights of the respondent and complainant, allegation procedures, and outline of the inquiry and investigation processes.

The relationship between the present study and the HAL report (1) is also of importance given the similarity in populations sampled and the period of time in which the studies were

conducted. First, while the HAL report noted that the policies typically covered the research and scholarly activities of all stakeholders at an institution, it did not provide relevant statistics. Our study found that all RIM policies included faculty members within their scope, but only about three quarters explicitly included students or external affiliates (70.7% and 73.2%, respectively); that more than a quarter of university stakeholders are not unambiguously included in the remit of these policies has important implications for addressing cases of misconduct. Moreover, as the actions of university administrators can have impacts on research activities, it seems reasonable to consider including administrators explicitly within policy applicability statements.

A second important difference between the HAL report and the present study is evidenced in terms of the types of misconduct identified. Although both studies observed similar coverage in terms of fabrication, falsification, plagiarism, and conflicts of interest, the HAL report observed greater inclusion of authorship concerns whereas we observed greater inclusion of funding issues and research ethics norms.[6] Our study also observed a greater inclusion of other forms of misconduct than did the HAL report, but this finding may be attributable to the smaller number of forms of misconduct considered in our study. For instance, improper data management and retaliation were examined in the HAL report whereas our study did not assess these forms of misconduct explicitly.

Finally, both the HAL report and our study found that most RIM policies were distinct from other policies, with only a small number of such policies being integrated into collective agreements and research ethics documents. The two studies thus show many similarities in the components of research misconduct policies. However, perhaps more informative are the differences that appear to be characteristics of the sample populations used in each review: the fact that types of misconduct differ and that policies do not necessarily include all relevant stakeholders represent important differences that merit further investigation. More specifically, we should consider the factors that might produce these differences (e.g., institution, amount of funding received, average of faculty publications).

Considerations and Future Directions

A final point concerns the nature of the institutional-based mechanisms for promoting research integrity and managing research misconduct in Canada. At present, Canadian universities have no alternative but to investigate cases themselves. This is a time consuming and expensive process. Moreover, there is an inherent and potentially problematic conflict of interest associated with an institution (through delegated committees) conducting an investigation into its own employees' activities while also remaining an impartial arbiter of employee conduct, something that could affect the institution's credibility (3,22). Conversely, conducting an investigation at an institution where allegations arise brings with it the benefit of familiarity with the parties involved. Clearly, these two concerns need to be balanced.

The findings presented in this paper demonstrate that the research integrity/misconduct policies of Canadian academic institutions are similar in scope and content to those implemented in the U.S. (4,6). However, unlike the U.S. with its Office of Research Integrity, there is no centralized body in Canada that can assist with the proceedings of an investigation and provide arms-length support. Existing Canadian university policies, in combination with the TCPS-IRS, may well suffice for dealing with research misconduct. Some authors, however, have suggested that serious consideration be given to how (or whether) systemic changes can be made to improve the governance of research in Canadian universities (2,23). Our

[6] Our category of research ethics subsumes confidentiality, which was explicitly assessed in the HAL report (1).

study focused on only one aspect of the mechanisms used to address issues of research integrity and misconduct, that is, the nature and content of misconduct policies. Future work should be aimed at providing a deeper ethical analysis of research integrity/misconduct policies and their implementation, in order to evaluate the effectiveness of these measures in both preventing misconduct and in promoting research integrity.

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Conflict of interest policies at Canadian universities: clarity and content

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Original version: Williams-Jones B, MacDonald C. Conflict of interest policies at Canadian universities: clarity and content. Journal of Academic Ethics. 2008;6(1):79-90.

Abstract

Discussions of conflict of interest (COI) in the university have tended to focus on financial interests in the context of medical research; much less attention has been given to COI in general or to the policies that seek to manage COI. Are university COI policies accessible and understandable? To whom are these policies addressed (faculty, staff, students)? Is COI clearly defined in these policies and are procedures laid out for avoiding or remedying such situations? To begin tackling these important ethical and governance questions, our study examines the COI policies at the Group of Thirteen (G13) leading Canadian research universities. Using automated readability analysis tools and an ethical content analysis, we begin the task of comparing the strengths and weaknesses of these documents, paying particular attention to their clarity, readability, and utility in explaining and managing COI.

Acknowledgements

We thank the valuable research assistance of Elise Smith, Vincent Couture, Ashley Pringle and Aimee Smith who helped with background literature reviews, data collection and summary analyses. This study was supported by a grant from the Institute of Genetics of the Canadian Institutes of Health Research.

Introduction

Conflict of interest (COI) can happen in a variety of professional and institutional contexts, and may manifest itself differently depending on the particular responsibilities of the professionals or institutions involved (1). It is thus increasingly common for organizations of all kinds — including corporations, universities, non-profit organizations, and government departments — to promulgate COI policies specific to their own work and context.

In the regulation of COI, as in the regulation of other ethically complex problems, the promulgation of policy documents is at best a partial solution. It is widely recognized that such documents are never panaceas: even the best policies have gaps and are subject to being misunderstood, overridden or simply ignored. It is thus essential not only that members of organizations be educated about the existence and content of various policies, but also that leaders work hard to foster suitable ethical cultures within their organizations, such that ethics policies (including COI policies, amongst others) are acknowledged, talked about, understood and ultimately respected.

But to say that policies are never sufficient is not to say that they are unimportant. Such documents can educate, guide, and serve as a focal point for discussion. The individuals that inhabit organizations always have a range of interests and obligations, and those interests and obligations are bound, from time to time, to conflict. Sometimes, such conflicts can be avoided, if the individuals involved are suitably aware of the relevant worries and take precautionary measures. In other cases, such conflicts cannot be avoided, and those involved must do their best to mitigate any negative effects for the organization and its stakeholders.

In either case, a clear and comprehensive policy document serves the dual purpose of educating and guiding the individuals involved.

The focus of the present paper is on the specific issues raised for academics and for the governance of COI in the university context. We begin with an exploration of the various ways in which COI can arise in university settings. Next, we review and assess the COI documents of Canada's "G13" universities. This very preliminary assessment comes in two parts. First, we describe and assess the results of an algorithm-based readability analysis in order to provide a rough appraisal of the extent to which the policies are written in clear and accessible language. Second, we conduct a content analysis in order to determine whether the various policies include the specific content that we argue is required in order for a COI policy to be ethically robust and practical. These preliminary studies cannot of course be conclusive. But the inventory they provide constitutes the beginning, at least, of an attempt to explore the adequacy of various institutions' COI documents in a consistent and rigorous way. Given that such documents are so often taken for granted, and their content and readability seen as less important than their bare existence, we see these preliminary steps as crucial.

Conflicts of Interest in the University Context

Universities are no longer simply places of higher learning where professors dedicate their time to teaching and research, activities traditionally considered the first and second missions of the university. Universities now have a third mission, to engage in industry collaborations, knowledge transfer and technology development (2-4). Advocates of this third mission argue that greater industry involvement and collaboration in university research will provide, amongst other benefits, new funding streams to universities to make up for reduced public investment, stimulus for research collaborations, and translation of academic knowledge into marketable products that then stimulate technological and economic development. Proponents argue that collaborative research and knowledge transfer can contribute to broader social goods (e.g., economic development, access to new technologies) while also generating funds to support university research and infrastructure.

Opponents challenge this enthusiasm, arguing that university-industry relations, particularly relations involving patents and spin-off companies, can foster a climate of secrecy amongst researchers and university administrators and undermine the pursuit of basic or fundamental research. Moreover, opponents note that such relations rarely generate the promised revenue streams — most knowledge transferred to the private sector is still far upstream in the commercialization process — and point out that there are only a handful of US universities making significant revenue from university-industry relations (5-7). More worrisome, perhaps, is the concern that such relations create damaging conflicts of interest for researchers, administrators and even entire institutions (8-10). An over-emphasis on commercialization and industry involvement in the university, critics argue, directly threatens the fundamental norms of academic freedom, objectivity and the open sharing of knowledge that underpin the university's respected place in society (11).

In this debate over the changing nature of higher education and the function of the university, concerns about COI have come to the forefront. A COI can be defined as "a situation in which a person has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties as, say, a public official, an employee, or a professional" (12). Such conflicts may be characterized as real or potential (i.e., an actual conflict of interest or a situation that threatens to evolve into a conflict of interest), and/or

apparent (i.e., perceived to be a conflict, whether real or potential). Even merely apparent COI can do significant damage to individual and institutional reputations, because even apparent COI maybe corrosive of trust. The primary concern is that COI in the university context threatens the objectivity, impartiality and credibility of judgments, whether in academic research or professional decision making, and leads to a subsequent loss of trust by staff, students and the broader public (13).

Discussions in the ethics, bioscience and health policy literatures regarding COI in university contexts have tended to focus on professors and clinical researchers working in medical schools. This is understandable, given the significant interaction between medical researchers and the pharmaceutical and biotechnology industries. Particular attention has been given to the influence that receiving consultation or patient recruitment fees, or having shares in biotechnology or pharmaceutical companies supporting clinical trials, can have on medical judgment and patient safety in biomedical research (9,14). Concern has extended more generally to the effect of such relationships on publication of scientific research in peer-reviewed journals, and to the need for transparency and for declaration of competing interests in order to promote objectivity (15,16). A cursory glance through the leading international bioscience and medical journals will find numerous discussions of the challenges posed by — and thus the need to regulate — individual and institutional conflicts of interest (13,17-19). The very real concern is that a range of institutional and commercial pressures are threatening the integrity of biomedical and clinical research. But COI in the university is diverse and extends well beyond the halls of biomedical or applied science departments, to include the humanities, law, engineering, and the social sciences.

In the university, COI tends to become a worry in situations in which professors or researchers have a financial or personal interest (e.g., in commercializing the results of their research) sufficient to appear to influence the objective exercise of their official duties, either as contributors to the shared body of knowledge or as educators. Yet COI is not limited to the research setting: teaching, administrative and support staff, and even students, may encounter situations in which they could be in real or apparent COI. For example, student teaching assistants may find themselves asked to grade their friends' exams; professors are required both to evaluate (i.e., grade) and to advocate for (e.g., to write letters of reference for) their graduate students; and many professors assign books they have written, and for which they receive royalties, as required course materials.

At the level of the institution, COI may arise when, for example, Heads of Department, Deans, members of Research Ethics Boards, or senior administrators (VP Research, President) feel pressured to support commercial or other agendas to the detriment of academic freedom or professional responsibilities (17,20). In its extreme form, implicit or explicit pressures on university administrators (e.g., to protect industry investments and interests) have led to the suppression of negative research findings, the gagging of researchers, and neglect of university researchers faced with legal challenges from industry partners, as in the Olivieri and Healy cases at the University of Toronto (18,21).

The most common method of mitigating the impact of a real, potential or apparent COI is to require the disclosure of interests. Once an individual's interests are transparent to the other parties involved in a decision- making process, it then becomes possible for those others to balance or judge the statements and decisions made by that individual in light of their disclosed interests. Ethically, there is a parallel here with the notion of informed consent in human subjects research: disclosure gives those involved the opportunity to consent — or not — to the individual's continued participation in the decision-making process. However,

it is generally acknowledged that many conflicts are sufficiently serious (e.g., in cases involving significant financial interests) that their influence cannot reliably be resolved by disclosure, audit or review. In such situations, often the only plausible solution is to remove the person from the situation in which their judgment is being trusted as independent and disinterested (22).

This threat to objectivity and public trust in professionals is considered sufficiently serious that many if not most professions have codes of ethics or codes of conduct that warn against COI. Whether the profession is formally licensed and self-regulating (e.g., medicine, nursing, engineering, accounting), or voluntary and unlicensed (e.g., university professors in general or specific academic disciplines), professionals are enjoined to aim for the highest standards of personal and professional integrity, to be aware of their significant social obligations and to behave in a manner worthy of public trust (1). In the case of university professors, norms of objectivity, academic freedom, and collegiality may also be made explicit in university codes of conduct or ethics guidelines. However, very few ethics codes define 'conflict of interest' or provide guidance on how to avoid or mitigate such conflicts (22).

A widely used means of managing COI in the university context is through the promulgation of specific COI policy statements, regulations or guidelines. Yet as has become apparent through analyses of the implementation of informed consent documents in the clinical setting (23-25), and of codes of ethics for professionals and businesses (26-28), policy-based approaches to guiding or shaping ethical behaviour have serious practical limitations. Policies, whether dealing with research ethics or with COI, are often written in a legalistic style that is hard for even well-educated people to understand, and they are often geared towards mitigating institutional liability and so focus on listing 'do not' rules instead of providing positive guidance for addressing ethical challenges encountered. Further, these policies are often developed and implemented in a top-down manner with minimal grass-roots support or buy-in.

There have been a number of important surveys of the COI policies of major research universities in the United States (29-31), but attention has focused primarily on financial COI in the context of bioscience and university-industry relations. There has been surprisingly little attention to COI in academia in general, or to those conflicts that involve interests other than financial interests. And it is not clear, based on those studies, whether university COI policies in general are accessible and understandable, or how they are perceived by members of the relevant university communities. To whom do these policies apply? Do they apply to professors and other researchers, or to all employees? Is COI clearly defined in these documents, and are procedures laid out for avoiding or remedying such situations? To begin addressing these important ethical and governance questions, we analysed the COI policies of thirteen major research universities in Canada.

Methods: Analysing COI Policies in the G13 Universities

Our study reviewed the COI guidelines or policy statements at the Group of Thirteen (or "G13") research universities in Canada. Similar to the American Ivy League or Big Ten, the Canadian G13 universities have the largest student enrolments, endowments, and research incomes among Canadian universities, and have national and international reputations for research and teaching (see Table 1). Most of these universities have medical and engineering schools, and undergraduate and graduate programs in most academic disciplines. Significantly for our purposes here, they also have Technology Transfer offices to facilitate university—industry collaborations, and professors and researchers who are actively

involved in knowledge transfer and commercialization. Such being the case, we would reasonably expect these universities to have policies or guidelines that address COI.

Table 1: Canadian G13 Universities

University	Location	Founded	Full-time students	Endowment	Research income (per annum)
University of Alberta	Edmonton, Alberta	1908	30,342	$577 million	$360 million
University of British Columbia	Vancouver, BC	1908	34,295	$714 million	$363 million
University of Calgary	Calgary, Alberta	1966	24,241	$293 million	$251 million
Dalhousie University	Halifax, NS	1818	13,180	$301 million	$93 million
Université Laval	Quebec, Quebec	1663	26,760	$112 million	$280 million
McGill University	Montreal, Quebec	1821	25,733	$765 million	$543 million
McMaster University	Hamilton, Ontario	1887	19,633	$340 million	$246 million
Université de Montréal	Montreal, Quebec	1878	41,349	$105 million	$384 million
University of Ottawa	Ottawa, Ontario	1848	25,093	$76 million	$190 million
Queen's University	Kingston, Ontario	1841	16,628	$505 million	$175 million
University of Toronto	Toronto, Ontario	1827	59,148	$1.5 billion	$624 million
University of Waterloo	Waterloo, Ontario	1957	22,604	$97 million	$110 million
University of Western Ontario	London, Ontario	1878	28,560	$199 million	$191 million

Source: 2004 data from a survey by CAUT (32).

Our initial supposition was that we would find one or a few key policy documents at each university that address COI for researchers and administrative staff. In fact, across the thirteen universities we examined, we found a wide variety of documents and diverse policy approaches for dealing with COI. These varied from very general statements of principle to brief discussions of COI in other documents (e.g., in guidelines on research ethics or on academic integrity), to focused COI policies for academic and/or non-academic staff, research assistants, and students. This diversity of documents reflects the often complex informational and regulatory context in which individual universities manage COI.

To focus our analysis, we restricted our review to those core policies that specifically target faculty members, or when those were unavailable, to policies that applied to university employees in general (and therefore to faculty members as well). There are of course other important categories of COI that are of interest at Canadian universities; consideration of those is beyond the scope of this paper. Each of the thirteen university websites was visited twice (in July 2006 and again in March 2007) and their key COI policies were identified and downloaded. These documents were then subjected to two types of analysis: 1) an automated readability analysis (Table 2), and 2) an ethical content analysis (Table 3). Our goal was to examine, in a preliminary way, the ethical strengths and weaknesses of these documents, with particular attention to their clarity and readability, and their utility in explaining and managing COI.

Readability analysis

Readability is a crucial feature of any policy document. If a document cannot easily be read, interpreted, and understood, little else about it matters. The relative ease or difficulty of a written text can be evaluated quantitatively through the application of mathematical algorithms that analyse, amongst other elements, the length of sentences, number of syllables per word, average word length, etc., in order to produce a readability score. To evaluate the readability of the university COI policies, we used an open-access online readability testing service provided by Juicy Studio which combines three well known algorithms: the Gunning Fog Index, the Flesch Reading Ease Index, and Flesch-Kincaid

Readability Test (33). The Gunning Fog Index estimates how many years of schooling would be required to understand a text. Standard benchmarks in this regard include 8-10 years for popular novels, 10-14 years for newspapers and magazines, and 15-20 years for academic publications. The Flesch Reading Ease uses a 100-point scale, with 100 being the easiest to read; websites, for example, are recommended to aim for 60-70 points. The Flesch-Kincaid scale, like the Gunning Fog, ranks according to education level, but on a 12 point/grade spectrum with 12 being the most complex. It should be noted that for Gunning Fog and Flesch-Kincaid, a lower score means that a text is easier to read, while for Flesch Reading Ease the inverse is the case with a higher score denoting greater readability (34).

Each university COI policy was copied into a Microsoft Word document to strip it of idiosyncratic formatting and ensure standardisation (e.g., to remove unnecessary line breaks); we then converted the policies into individual HTML pages (as required by the software) and subjected them to the online readability analysis. The readability scores for each university policy were compiled and given a rank from easiest to read (1) to most difficult to read (12) for each of the readability tests, and then were compiled to provide an aggregate score and overall ranking for each document (see Table 2). As the readability tests only work for English language texts, we were unable to evaluate the Université Laval's COI policy, which was only available in French, so policies were ranked from 1 to 12 instead of 1 to 13. The Université de Montréal has an English translation of its policy which we included in the analysis, although only the French policy is considered official by the university.

Table 2: Readability Analysis of University COI Statements

University	Total words	Average words/ sentence	% of words with 3+ syllables (%)	Gunning Fog Index	Gunning rank	Flesch reading ease	Flesch rank	Flesch-Kincaid grade	Flesch-Kincaid rank	Aggregate score	Aggregate rank
Alberta	911	6.75	30.19	14.77	9	36.73	12	9.81	11	32	11
British Columbia	3748	5.51	27.85	13.35	4	45.94	5	8.22	2	11	3
Calgary	771	4.91	25.94	12.34	1	46.7	3	7.97	1	5	1
Dalhousie	4197	7.34	28.12	14.18	8	42.48	7	9.16	7	22	7
Laval	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
McGill	772	7.28	27.98	14.10	7	41.53	8	9.28	8	23	8
McMaster	785	7.20	27.26	13.79	5	42.93	6	9.06	6	17	6
Montréal	1015	7.36	25.75	13.23	2	48.92	2	8.26	3	7	2
Ottawa	898	6.96	30.62	15.03	10	40.46	10	9.35	9	29	9
Queen's	1912	8.17	29.45	15.05	11	40.89	9	9.59	10	30	10
Toronto	2693	7.44	25.66	13.24	3	46.36	4	8.64	5	12	5
Waterloo	1798	7.55	30.87	15.37	12	37.21	11	9.95	12	35	12
Western Ontario	657	8.53	26.03	13.82	6	48.93	1	8.55	4	11	3

Readability analysis performed using tools provided by Juicy Studio (34). Gunning Fog measures years of schooling required; Flesch Reading Ease uses a 100-point scale, with 100 being the easiest to read; and Flesch-Kincaid grade measures required level of education (grades 1-12).

An obvious limitation of these readability tests is that purely mathematical evaluation of a text is by no means definitive: these tests can only provide a rough measure. Moreover, when considering the readability of university COI policies, it must be acknowledged that the reader — for our purpose, university professors and staff — will typically be very well educated and should have little difficulty in comprehending even very complex texts. However, as will be discussed below, many of these policies may still be rather challenging for even educated individuals to understand, due to their often-legalistic language, which is to some extent reflected in the ranking provided by the readability tests. Quantitative readability analyses have been used to good effect to study related documents, such as informed consent forms (35), patient information websites (36), and academic

textbooks (37). As an analytic tool, then, a readability test can be a useful means of evaluating the relative ease or complexity of a given text, and for our purposes, to compare and rank the conflict of interest policies of the G13 universities.

Upon examining Table 2, the first thing to note here is that there was relatively little variation, in terms of readability, among the various policies. On the Gunning Fog index, for example, the years of schooling required to understand the various policies ranged from 12.34 years (University of Calgary) to 15.37 years (University of Waterloo). Similarly, on the 100-point Flesch index, scores varied from a low of 36.73 (University of Alberta) to a high of 48.93 (University of Western Ontario). And on the Flesch-Kincaid scale, policies ranged from 7.97 (University of Calgary) to 9.95 (University of Waterloo). Thus the absolute differences between policies were relatively small. However, the aggregate rankings do reveal patterns. The University of Waterloo's policy, for example, scores at the bottom of the aggregate ranking because it ranks at or near the bottom on each of the three scales. That is, Waterloo's policy is consistently (though not tremendously) harder to read than, say, The University of Western Ontario's.

It is also worth noting that while the differences among policies were not large, none of the policies scored very well, and most of them have readability levels outside of the desirable range. Note for example that on the Gunning Fox Index, a score of 10-14 is recommended for newspapers and magazines. Yet Alberta, Dalhousie, McGill, Ottawa, Queen's, and Waterloo all had scores higher — i.e., worse — than that. Thus all of those policies are less readable than what is considered acceptable for magazines. It might be argued, of course, that that is a poor comparison, and that most of the persons reading these policies will be sufficiently highly educated that they ought not have any trouble understanding documents slightly more complicated than a magazine article. Such a response would be unfortunate, however. Instead of defending these documents, policy-makers ought simply to work harder at making them more readable. It is also worth noting that we are in no way arguing that COI documents should be maximally simplistic. Simplicity might well be achieved at the expense of clarity. But none of the documents examined were at risk of being accused of excessive simplicity: all were quite complex. It is worth asking, at least, whether the authors of these documents even considered (in any rigorous way) whether their documents were in fact readable.

2) Content analysis

Each university COI policy was read and analysed to see whether it included five major elements that we considered essential for a policy to be ethically robust and practical (See Table 3):

1. *Date the policy was approved and/or revised*: When the policy was produced or updated is an important marker of its relevance and ability to harmonize with more recent government policies and evolving 'best practices.'
2. *Definition of COI*: A clear explanation of what constitutes a COI is essential for a policy to be useful, given that COI may be complex in both its form and resolution.
3. *Examples of COI*: A logical corollary to a definition, examples will be critical to helping a reader understand and recognise COI in diverse settings.
4. *Procedures to follow in the event of COI*: Once a COI has been identified, there should be an explanation of the mechanisms by which it should be managed and resolved.
5. *Further information on COI*: Additional sources of information, such as examples, more detailed procedures, related ethics guidelines, etc., would help operationalize a COI policy.

Table 3: Ethical Analysis of University COI Statements

University	Scope	Approved and revised	Definition	Examples	Procedures	Pointers to further Info
Alberta	All members of university	2003	Y	N	Y	Y
British Columbia	Faculty, staff, researchers, etc.	1992 Rev 2005	Y	Y	Y	N
Calgary	Staff, students, fellows, researchers	1987 Rev 2001	Y	Y	N	N
Dalhousie	All employees	2002	Y	Y	Y	Y
Laval	Researchers (including professors and students)	1995	Y	Y	Y	N
McGill	All members of university	1997	Y	Y	Y	N
McMaster	Faculty	NA	Y	N	Y	Y
Montréal	Teaching and nonteaching personnel	1993	N	Y	Y	N
Ottawa	All members of university	1995 Rev	N	Y	Y	Y
Queen's	Staff not in Faculty Association	1995 Rev 2001	Y	Y	Y	N
Toronto	Academic staff	1994	Y	Y	N	N
Waterloo	All members of university	1991	Y	Y	Y	Y
Western Ontario	Faculty and staff	2000	Y	Y	Y	N

One of the premises of our analysis here is the idea that COI documents ought to be more than simply policies whose very existence is hoped to mitigate legal liability. Mitigation of liability is of course an important goal. But more important is the provision of clear and comprehensive guidance to the university community, in order to make sure that members of that community, and the university as whole, are able to meet their ethical obligations.

An *ideal* COI policy would be current, would define and give examples of COI, would clearly explain how to avoid COI where possible and how to mitigate dangers where avoiding COI proves impossible. Further, an ideal policy should recognize its own limitations, and hence provide readers with guidance regarding where to look for additional information. The ideal policy would be relatively comprehensive yet still reasonably concise, would be written in an accessible and not overly legalistic style, and would focus on educating readers and on encouraging ethical behaviour.

How do the 13 policies we examined stack up to this ideal standard? Most policies (12 out of 13) did provide a definition of COI, most gave examples (11 out of 13) and most explained procedures for dealing with COI (12 out of 13). Far fewer provided links to additional information (just 5 out of 13). Most of the policies were legalistic in style and language, and most focused on listing prohibitions as well as procedures for mitigating institutional liability. Only 2 of the 13 policies, those of Dalhousie and Waterloo, featured all 5 of our desiderata. We suggest that, strictly in terms of content, the four best policies were those from Dalhousie, Waterloo, Queen's, and British Columbia. Generally, though, we found these 13 documents to be lacking in appropriate content. Most of them provided definitions, but those definitions were not always clear (a full analysis of the shortcomings of these definitions is beyond the scope of this paper.) Some policies mixed examples into their definitions, but many of them provided no examples at all. Most documents indicated the existence of procedures for dealing with COI, but often those procedures were not well explained, and often no indication was given as to where to find more information about those procedures. In one case (McMaster), there were diverse but disconnected sources of information on COI but no central policy — the most detailed information was found in the faculty handbook section on research ethics (which is what we analysed). Interestingly, McMaster did have a coherent COI policy for non-academic staff. Finally, very few of the policies provided readers with

links or other pointers to further information about COI, so those policies miss out on a crucial opportunity to work as educational documents, rather than (solely) as guides for short-term decision-making.

It is interesting to note that there is no apparent correlation between our readability and content analyses. The best policies in terms of readability (University of Western Ontario and University of Calgary) were both very short: each features only a rudimentary definition of COI, and each is thin on examples and details. Conversely, the most comprehensive policies in terms of content — namely Dalhousie and Waterloo — ranked 7th and 12th respectively in the readability analyses. This is part of a larger pattern: legalistic texts had better readability rankings, likely because they feature shorter sentences (e.g., bullet-pointed items) and shorter overall length. This might reflect a weakness in the automated analysis: though legalistic texts might well tend to have shorter sentences, and although shorter sentences tend to be very readable, jargon-laden legalistic documents are notoriously difficult for most people to read. More generally, however, the disconnect found between readability and comprehensiveness reminds us that writing an effective policy document is a complex optimization problem, requiring careful attention to detail and, ideally, an iterative process of drafting, testing, and re-drafting.

Conclusion

It seems quite likely that many problems related to COI result from individuals having a poor understanding of the relevant institutional guidelines and procedures and a belief that they can manage COI on their own (31). While the questions of personal bias and individual integrity — which so often dominate discussions of COI — are important, addressing them can only be part of the solution. There is, we suggest, a need to emphasize awareness of the situational aspects of COI: that is, COI policies should help members of the academic community (faculty, administrators, non-teaching staff, students) understand the specific contexts in which COI occur (e.g., various academic departments, research or teaching settings); discern the different types and severity of COI (e.g., financial, prestige, or familial relations), and then choose the appropriate responses (i.e., disclosure, withdrawal or avoidance). As MacDonald, McDonald & Norman note, there is nothing necessarily blameworthy about finding oneself in a COI; sometimes institutional arrangements make COI likely, even inevitable (12). What matters, ethically, is that individuals and institutions deal appropriately with COI when it arises. Good COI policies are an obvious first step in that direction.

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Legalistic vs inspirational: comparing university conflict of interest policies

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Original version: Smith E, Williams-Jones B. Legalistic vs inspirational: comparing university conflict of interest policies. Higher Education Policy. 2009;22(4):433-59.

Abstract

In response to growing public and policy concern about conflicts of interest (COI) in university research, academic institutions in North America and Europe have introduced policies to manage COI. However, depending on their form and content, COI policies can be more or less helpful in the effective management of COI. In this paper, we examine and compare the design and content of COI policies at two Canadian research universities (the Université de Montréal and the University of Waterloo), which we suggest, exemplify two general categories or poles on a spectrum of policy approaches. We describe 1) a legalistic approach that promotes a concise but rigid structure, and 2) an inspirational approach that encourages principle-based deliberation and wider interpretation. Each of these approaches has its particular strengths and weaknesses. We conclude with some recommendations to help administrators and policy makers improve the quality, utility and effectiveness of university COI policies.

Acknowledgements

We thank Chris MacDonald for his helpful comments on this manuscript, and the anonymous reviewers for their insightful and constructive critique. We also acknowledge the valuable research assistance of Vincent Couture, Ashley Pringle and Aimee Smith who helped with reviews of background literature, data collection and summary analyses. This research was supported by grants from the Faculty of Medicine of the Université de Montréal (Smith received a COPSE fellowship, and Williams-Jones a start-up grant), and the Institute of Genetics of the Canadian Institutes of Health Research.

Introduction

Academics and policy makers in North America and Europe are increasingly concerned about the risks associated with conflicts of interest (COI) in the University (1-3), and most institutions have responded by introducing COI policies and guidelines. However, as we will show through a comparison of COI policies at two Canadian universities, not all policies are created equal. Depending on their form and content, COI policies can be more or less helpful in the effective management of COI situations.

A COI may be defined as “a situation in which a person has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties as, say, a public official, an employee, or a professional” (4). Such conflicts may be characterized as real or potential (i.e., an actual COI or a situation that threatens to evolve into a COI), and/or apparent (i.e., perceived to be a conflict, whether real or potential). Even ‘merely apparent’ conflicts of interest can do significant damage to individual and institutional reputations and relationships.

In the university research milieu, COI occur primarily but not exclusively when researchers have a financial or personal interest (e.g., in commercializing the results of their research)

sufficient to appear to influence the objective exercise of their official duties either as contributors to the shared body of knowledge or as educators. As many scholars have noted, COI pose important ethical and policy challenges for faculty, staff, students and administrators (5-7); if left unaddressed, COI can seriously undermine the public's trust in professors and universities. But it should also be recognised that COI are not inherently unethical, and that sometimes, institutional arrangements make COI acceptable, even inevitable. So, in effect what matters, ethically, is that individuals and institutions deal appropriately with COI when they arise (4,8).

As with other large organizations (e.g., corporations, non-profit groups, government departments), universities have responded to the challenge by promulgating policies designed to manage or avoid COI. In the United States, the introduction of university COI policies was driven in part by federal government regulations (enacted in 1995) requiring that all research institutions seeking funding from the US Public Health Service, which includes the National Institutes of Health (NIH), to have internal policies and procedures to manage COI; the National Science Foundation (NSF) has a similar policy (9). All university faculty members applying for research funds from the NIH or NSF are required to disclose, to a designated member of their institution, any 'Significant Financial Interests' (e.g., financial relationships exceeding $10,000 in payment or 5 percent ownership in a company) that could cause or appear to cause bias to publicly funded research; however, setting such a formal limit may be somewhat arbitrary, and ignore the differences between individuals with regards to what amount of money is 'interesting' (10). These regulations provide a general structure and minimum set of standards for university COI protocols; more than 70% of US research institutions have subsequently implemented COI policies that go beyond the minimal federal government requirements (11). Like their American counterparts, most Canadian universities have COI policies, but they are not uniformly or comprehensively regulated by provincial or federal legislation that set out common minimum requirements (12).[1]

As with the regulation of other ethically complex problems, policy documents can provide only a partial solution to university COI. Even the most thorough documents will lack specificity and contain gaps in structure and content, and they are subject to being misunderstood, overridden or simply ignored (6,14,15). Yet good COI policies remain an obvious important first step in the right direction. The question, then, is what constitutes a good — or even an ideal — university policy?

It is probably unrealistic, and maybe even misguided, to aim for a single one-size-fits-all model or ideal a university COI policy; universities in even one country may be simply too different in structure and function. If one looks, for example, at universities in Canada and the US, it is evident that there is great diversity in institutional mandate and culture: universities may be focused primarily on teaching, research, or professional training (or some combination thereof). They may also operate within very different legal contexts, as in the case of state vs. privately funded institutions where faculty members are employed by the state (also the case in some European universities) or by the institution (common in private institutions in the US, and all Canadian universities). Finally, given a variety of US state and

[1] One exception is COI in research involving human subjects, which is governed by provincial legislation (notably in Quebec, which has specific provisions in its Civil Code) and by national policies such as the Tri-Council Policy Statement on Ethical Conduct for Research Involving Human Subjects (13). These instruments regulate research in Canadian universities that receive funds from provincial and national granting councils.

Canadian provincial legislation, faculty may be subject to different requirements with regards to their conduct within and beyond the borders of the university.

Important lessons can, however, be drawn from a close examination of how particular university policies seek to address COI in practice. In this paper, we compare the COI policies of two Canadian universities: the Université de Montréal and the University of Waterloo. These two policies exemplify, we suggest, two general categories or poles along a spectrum of policy approaches used by Canadian research universities (and possibly universities in the United States and Europe). That is, we propose that COI policies can be usefully thought of as being more or less *legalistic* (Université de Montréal) or *inspirational* (University of Waterloo) in style and content. Our comparison pays particular attention to the policy's accessibility and layout, its general philosophy and preamble, and discussion of rules, definitions, examples, and procedures to address COI. We conclude that both the legalistic and inspirational styles have important merits and limitations. Our primary aim, in this paper is to highlight the importance of developing good (i.e., useful, effective, relevant) COI policies, and to provide practical guidance to administrators and faculty involved in the revision of existing or drafting of new COI policies.

A Comparison of Two Policies

The development and implementation of university COI policies reflects the particular legal contexts of universities (e.g., public or privately funded, independent or state regulated), as well as the governance decisions of administrators regarding the management and avoidance of COI situations. A 2006 pilot study of COI policies at 13 leading Canadian research universities uncovered a broad range of documents, from very general statements of principle, to brief consideration or mention of COI in a sub-set of other documents (e.g., in guidelines for research ethics or academic integrity), to focused COI policies for academic and/or non-academic staff, research assistants, and students (16). Not surprisingly, perhaps, these policies also differed substantially in style and content.

This diversity of COI policy styles can, we suggest, be usefully grouped into two rough categories, i.e., those that are *legalistic* or *inspirational* in nature.[2] By 'legalistic' we mean those policies that are written in a relatively rigid, legal language and style and that are organised as a set of rules and procedures to follow. We contrast this with policies that we define as 'inspirational' in nature; that is, they are written in a common and accessible language, and lay out guiding principles and flexible procedures.

To be clear, these are not the only possible categories; there may be other useful ways of grouping or organising the diversity of university policies. Further, if one accepts our two rough categories, it is important to recognise that they are not rigid or precise. Our preliminary study of Canadian university COI policies has shown that policies are spread along a continuum, with 'legalistic' and 'inspirational' at opposite poles. Between these two poles, policies may blend items from both styles, creating hybrid documents that are more or less legalistic or inspirational. Finally, even policies at the poles — such as the two presented in this paper (i.e., those of the Université de Montréal and the University of Waterloo) — will not be uniformly legalistic or inspirational. Nevertheless, as we will show in the following analysis, the two rough categories of legalistic and inspirational provide a

[2] In the pilot study of Canadian universities, the COI policies were evenly split between the legalistic (7/13) or inspirational (6/13) styles.

useful point of reference or framework with which to examine and compare the strengths and limitations of different approaches to governing COI in the university context.

Policy Style

The COI policies of the Université de Montréal (hereafter Montreal) and the University of Waterloo (hereafter Waterloo) differ substantially in their structure and style (see Appendices 1 & 2 for the complete policies). Montreal's policy is concise, structured and legalistic, while Waterloo's policy is a longer, more readable and inspirational document. Montreal's policy, which was adopted in 1993, consists of only 4 pages and a total of 998 words.[3] It is highly structured, composed of 8 numbered Articles (Application, Rules, Conflict of Interest, Procedure for Disclosure, Treatment of Disclosures, Appeals Committee, Application of Regulations, and Coming into Force), each of which is substantiated through numbered sub-clauses or statements. The language is formal, even rigid, consisting of declarations or affirmations of what constitutes (or does not constitute) appropriate behaviour in relation to COI (e.g., 'do not' or 'personnel shall' language).

By contrast, Waterloo's policy, introduced in 1991 and amended in 2000, is much longer at 1799 words and more loosely structured; it includes only four subcategories (Preamble, General Philosophy and Procedures, Examples, Development of Guidelines and Procedures on Conflict of Interest). The language is much less formal (no numbered articles or clauses) and more readily understandable; also, the Waterloo document consists of longer sentences and paragraphs. The style and vocabulary allow for greater interpretation and require the reader to reflect on, rather than simply comply with, detailed rules and procedures.

Preamble and General Philosophy

Most institutional policies begin with a preamble or introduction that states the purpose and sets the tone or general philosophy of the document. Both the Montreal and Waterloo COI policies state their intention to provide adequate regulations for university staff in order to protect both staff and the institution. More explicitly, Montreal's policy applies to "teaching and non-teaching personnel" while Waterloo's policy applies to "faculty and staff members"; other Canadian university COI policies sometimes include students or "all members of the university" within their scope (16). It is interesting to note that the Waterloo policy also includes a simple definition of COI in its preamble, stating that a COI "exists when a member of the University is or may be in a position to use research, knowledge, authority or influence for personal or family gain or to benefit others to the detriment of the institution" (17).

It is clear in the preamble of the Montreal and Waterloo policies that the aim is to mitigate the risks of COI, particularly loss of objectivity, which can result in biased research, and the erosion of perceived and actual impartiality of and confidence in staff and the institution. The protection of staff and the institution is to be achieved by safeguarding and respecting a set of values. For example, Montreal's policy states in the Preamble, that "To ensure transparency and integrity while at the same time respecting the autonomy of the university, the Université de Montréal has decided to adopt regulation for avoiding conflict of interest situations and, where necessary, protecting both university staff and the institution itself" (18). The main values here are autonomy (of the institution), transparency, and integrity of staff.

[3] This policy was, until the summer of 2007, available on the University website (in PDF format) in both French and English although only the French document is legally binding. To facilitate comparison, we have referred to the English-version of the policy, on file with the authors and presented in Appendix 1.

Waterloo's COI policy similarly highlights the importance of integrity. "Whatever the nature of the external activities or relationships, the University expects each of its members — faculty, staff, student or officer — to act in a manner consistent with a high standard of integrity and ethical behaviour" (17). In addition, it outlines a greater number of values such as ethical behaviour, the university's reputation, and the importance of "transfer[ing] knowledge, discoveries, and technology to society for its benefit" (17). In order to promote such values, the Waterloo policy notes that it has chosen regulation to avoid COI that can harm the university's goals; however, it also stipulates that the mere existence of COI does not imply that an activity must be prohibited. Seeking counsel and determining appropriate behaviour in a specific situation allows the university and the individual to properly manage the COI.

While there is much overlap in the values put forth by both universities, Waterloo establishes many more principles in its policy. This principle-based approach sets out the fundamental rationale, the reason *why* it is important for the university to have a COI policy. It also establishes a framework for deliberation and interpretation with respect to various situations. Procedures are found in the section entitled "General Philosophy and Procedures" which encourage reflection and dialogue on campus to foster appropriate understanding and management of COI. This provides greater latitude of decision-making and action than the more rigorous and rigid procedural approach of the Montreal policy.

The Waterloo approach avoids prescriptive directives, such as statements that staff 'must' negotiate or disclose information, as found in the Montreal policy. Rather, the Waterloo policy emphasizes that COI is sufficiently important to manage or avoid, "that members should, of their own volition, take the initiative in disclosing conflicts or potential conflict of interest situations." In this manner the university seeks to promote transparency, responsibility, open negotiation and consensus. This more inspirational style aims to encourage willing participation rather than adherence to rules and it is also an endorsement or expression of trust in the ethical conduct of employees. Conversely, the Montreal document is definitional at the outset. Stating *what* the COI policy is, the Preamble (and the rest of the policy) is succinct and unambiguous and avoids any philosophical questioning about the nature of COI. It specifies intent and limits interpretation through the use of clear, directive statements such as "do not," "personnel shall avoid" or "personnel shall be obligated to."

The processes or mechanisms established by these two universities to deal with COI are consistent with and reflect the style of their policies. While they both state that disclosure is necessary, Montreal requires that staff avoid COI and focuses more narrowly on instructions to staff on what to do when confronted with COI; Waterloo requires that staff avoid or manage COI depending on the situation and explains why such a process is important. The latter obviously provides a more flexible, adaptable approach. The consequences of these differences in approach become more evident on closer examination of the general rules of the two policies. But before looking at the rules, it is important to examine more closely the means by which the two policies define and explain COI.

Definitions

Arguably, many individuals in academia think of COI in relation to scandals in medical practice or improper relations with the pharmaceutical industry, for example, in the Jesse Gelsinger case in the United States or the Olivieri and Healey cases in Canada (19,20). However, many COI occur without any dramatic aftermath or media attention. To properly

identify all types of COI, it is obviously important for policies to include a definition of COI, as well as a lexicon of terminology used throughout the document (21).

The Montreal policy does not provide an explicit definition of COI, nor does it define other important concepts such as potential or apparent COI; instead, a list of examples is given in which a "conflict of interest may arise" for members of the personnel. This failure to define key concepts exemplifies how even an apparently very legalistic policy (in terms of language and style) may not be 'uniformly legalistic' or a perfect fit with our proposed categories; it also, however, points to important weaknesses in terms of the structure and content of this policy. Waterloo's policy, on the other hand, provides a short definition of COI at the beginning (in the Preamble) and a longer definition mid-way through the document. As mentioned previously, the first definition reads as follows: "A conflict of interest, or a potential conflict of interest, exists when a member of the University is or may be in a position to use research, knowledge, authority or influence for the personal or family gain or to benefit others to the detriment of the institution." Apart from mention of the institution, such a definition is fairly standard if not comprehensive. For example, the definition omits reference to apparent COI. On the other hand, the second definition in the Waterloo policy is broader and defines, in some detail, individual COI (as well as institutional COI and conflict of commitment).

> *Individual* conflicts of interest often derive directly or indirectly from opportunities to participate in externally funded research and in a subsequent interplay between the results of the research and a faculty member's personal or financial interests. Such situations frequently place faculty and staff members in a position to manage contracts, select equipment and supplies, involve graduate students in sponsored research or play administrative roles which demand the utmost in integrity and honesty. Even the appearance of an apparent conflict can have a negative impact on the University and the individual in the eyes of the community. (17)

Although this definition is broader than the first, it may not be considered as comprehensive because it concentrates mostly on financial COI. But what, then, is an appropriate definition of COI? There is an extensive literature on what should constitute a precise definition of COI. Yet despite broad philosophical agreement on the key elements of COI, there remains debate over whether the heart of the issue lies in the risk of corrupting individual *judgment* or in the risk to the *interests* of the client or institution (22). We will leave these debates aside and simply suggest that any definition should be simple to understand yet sufficiently comprehensive and broad to capture key COI situations. The various types of COI — real, potential, and apparent COI — may be best illustrated or described through specific examples.

Prior to examining specific examples mentioned in the two university COI documents (see the following section), the concept of institutional COI and conflict of commitment addressed in the Waterloo policy should be considered. Conflict of commitment is defined in the policy as "any external activity or undertaking which places an individual in a position which: interferes with or prevents the discharge of her-his University responsibilities, as defined by the individual's employment contract." In general terms, conflict of commitment can be thought of as "the umbrella term for issues centering on the allocation of time and energy to fulfill three primary academic roles: teaching, research, and public service" (23). In effect, a faculty member might be committed to too many research activities and public service and not dedicate sufficient time to their teaching, resulting in a conflict between external interests and primary professional or academic responsibilities and commitments. In the

interest of simplicity, conflict of commitment can be illustrated through examples and integrated within a general comprehensive definition of COI.

With regards to institutional COI, the literature generally acknowledges this to be an issue that should be further analysed and included in COI policies (24). The Report of the Association of American Universities provides some insight into this issue, with the following definition of institutional COI:

> An institutional financial conflict of interest may occur when the institution, any of its senior management or trustees, or a department, school, or other sub-unit, or a related organization (such as a university foundation) has an external relationship or financial interest in a company that itself has a financial interest in a faculty research project. Senior managers or trustees may also have conflicts when they serve on the boards of (or otherwise have an official relationship with) organizations that have significant commercial transactions with the university. The existence (or appearance) of such conflicts can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at the university. If they are not evaluated or managed, they may result in choices or actions that are incongruent with the missions, obligations, or the values of the university (25).

However, it must be noted that institutional COI is often intertwined with individual COI and as such is then regulated through the central university COI policy. It is worth questioning, however, whether institutional COI regulations should be included within central COI policies, which are often written to guide the behaviour of individual faculty members, staff or students. Do all university faculty and staff have a responsibility for their institution's interests? The obvious answer to such a question is 'yes'; yet in practice, things are somewhat more complicated.

Since institutional COI usually arise for and are the responsibility of the administrative staff (mainly senior administrators, such as Deans or Vice-Principals), the management of these COI are commonly out of the hands of most members of the university community. As such, these conflicts should most probably be addressed in a separate policy aimed specifically at administrative staff. This would allow policy makers — as well as the broader university community — to acknowledge and distinguish between institutional and individual COI; it might also enable the formulation and communication of simpler and more effective COI policies to the relevant stakeholders. McMaster University is one example of an institution that has a separate policy intended for non-teaching personnel and administrative staff, and that focuses to a large extent on institutional COI (26).

Examples

An individual COI — whether it be real, apparent or potential — is still a somewhat abstract concept, and so examples are important in order give a practical understanding of the nature and scope of COI. The examples in COI policies are naturally selective and representative rather than comprehensive. Further, although many COI policies may have a legalistic tone and structure, the management of COI remains an ethical challenge that cannot be captured entirely in legal wording or examples.

The examples in the Waterloo policy cover a number of situations and are broken down into the following categories: Favouring of Outside Interests for Personal Gain; Inappropriate Use of University Personnel, Resources or Assets; Inappropriate Use of Information; Conflict of Commitment; and Inappropriate Involvement in Appointment Process. These examples are

comparable to those found in the Montreal policy in terms of content, although they differ in style and form. For instance, in the Montreal policy, Articles 3.1a) to 3.1d) provide examples of possible COI that can arise through interactions with external enterprises. Article 3.1a) notes that a "conflict of interest may arise in cases where a member of the personnel: Directly or indirectly has monetary or other interest in an external enterprise that deals or is likely to deal with the University". In this example, enterprises are most likely interpreted as being for-profit businesses such as pharmaceutical or other technology companies. However, it is unclear whether non-governmental or charitable organisations would be included, and so the word 'enterprise' may unduly limit the scope of the policy. The vocabulary used in a policy must be precise but not overly limiting, or worse yet, misleading.

An important difference between the Waterloo and Montreal policies is that the examples provided in the former are described in far more detail and include a broader range of typical COI. The drafters of the Waterloo policy selected examples which demonstrate conduct that is clearly irresponsible, i.e., "headline conflicts." That is, they chose examples that are most often found in the media, such as "Directing the faculty member's government sponsored research program to serve the research or development needs of a private firm in which the faculty member has a financial or other interest" (17).

It should be noted that most of the examples in both policies have to do with financial COI, especially those that arise through researcher collaboration with the private sector. While an important issue, many COI in the university setting are not financial (16). For example, a student can be in a COI if, when working as a teaching assistant, he or she is asked to evaluate a friend's exam, as has been reported at the Université de Montréal (27). We may also find a non-financial COI if a member of staff uses confidential information acquired in the course of university activities to advance their personal interest, e.g., with regards to their or a family members' political activities.

Furthermore, while university-industry relationships that raise concern about COI may be more common in the applied sciences (such as pharmacology, medicine or engineering), this does not mean that COI do not occur in other faculties or departments. If an example in a general COI policy is to be useful and relevant for all staff, it should be adapted to the general university context. It is obvious that the university community is not homogeneous and that examples of COI in law schools may differ from those arising in medical schools or in the social sciences and humanities.

A judicious blend of the precise language of the Waterloo policy with the more comprehensive scope of the cases in the Montreal policy might be a useful approach. (The precise language of Waterloo, which is in a sense legalistic, and the comprehensive scope of Montreal, which is in a sense inspirational, further exemplifies the fluidity of these two categories.) This is the case with the Dalhousie University COI policy, where examples take the form of, for instance: "Cases in which a university member conducts or participates in a research project which may affect his or her financial interests or those of a related business" (28). This example does not restrict its explanation to an enterprise or limit the scope of the definition; it leaves room for interpretation without being too vague; and it is relevant to many university contexts, as much so in the humanities and social sciences as in the basic or applied sciences.

Rules

The rules outlined in the Montreal COI policy (18) oblige university personnel to "avoid any situation which may entail choosing between personal interests, monetary or other, and

those of the University" (Article 2.1). In cases where COI cannot be avoided, any real, potential or perceived COI must be disclosed to a responsible committee when teaching personnel are involved, or to a head of unit in cases involving non-teaching personnel (Articles 2.2 & 2.3). In those cases where the person who wants to disclose is in a COI with their head of unit or a member of the committee, they may refer their disclosure form to an appeals committee. In contrast, the Waterloo policy asks the individual to disclose all real or potential COI to their immediate supervisors and to seek counsel from these individuals. Both parties must come to an agreement to monitor, avoid or manage the situation.

The rigid and formal 'rules-based' regime of Montreal seems likely to be more problematic or difficult in its practical application. The strict requirement that staff avoid any COI (prior even to disclosure) seems simpler than the Waterloo process. Avoidance and prevention are prioritised over discussion and evaluation, a resolution that may be particularly appropriate in the context of 'significant financial interests', assuming that a clear definition can be given of such interests. Yet, a policy that requires personnel to first avoid all COI may be unrealistic, or worse yet, incoherent. Strictly speaking, if personnel are to avoid all COI, there seems little point in further discussing disclosure. Article 2.1 of the Montreal policy would have been better phrased as "All university personnel shall, *to the extent feasible*, avoid any situation…."

In a small department, for example, it may be difficult or even impossible to find completely impartial evaluators, thus COI in committee processes is inevitable. Further, by stating the necessity to avoid all COI situations, individuals may be dissuaded from disclosing issues that they are unable to avoid, thereby finding themselves alone to manage COI without support or counsel. Finally, a COI — especially one that is potential or apparent — can often be managed, assuming that there is a system in place that encourages disclosure, evaluation and dialogue. The Montreal policy seems to leave no room for such nuance.

Consider the following example: a professor decides to include in the required course readings, a book which he/she has authored, because of the financial gain that will accrue from royalties, instead of recommending or requiring an alternative or more appropriate text. This situation is an actual COI, because the professor's financial interests unduly influence the objective exercise of his/her duty, i.e., to provide the most appropriate text for the students. If on the other hand, the professor's book is the best material available for students and would be chosen regardless of whether the professor received royalties, the situation becomes more apparent than actual. Concerned about the apparent or potential COI, the university might choose to take strong or even coercive measures and forbid the use of this book. On the other hand, the university (or the professor) might choose to manage the conflict by donating the royalties to a student fund or a charitable organisation.[4]

A policy that strictly forbids professors from using their own books in their courses might prevent actual and apparent COI, but it would also be a significant infringement on academic liberty (e.g., the liberty to choose appropriate course materials) and may well disadvantage students who would then forego reading what might be a very appropriate text. Moreover, such a strict policy leaves little or no place for the consideration of potentially creative alternatives to managing COI, such as discussing the issue with students in order to arrive at a shared solution (e.g., donation of royalties to a charity); a potentially valuable teaching opportunity is thus lost.

[4] We thank Chris MacDonald for sharing this helpful example.

In the previous example, the management of COI on a case-by-case basis would allow for a more customized solution that could be to the advantage of both the professor and the students. The case-by-case COI management approach is best suited to evolving conditions and available resources; also, it can foster greater consensus about the management of COI among university staff. In such a situation, it may be more realistic and practical to choose to disclose in order to manage COI. Nonetheless, such a case-by-case approach also likely requires far more up-front discussion about COI and appropriate management strategies, and thus may be more complicated and costly (in terms of time) than a requirement to follow more rigid university regulations that require individuals to avoid all COI. Finally, as in the case of significant financial interests, there may be some types of COI that simply have to be prohibited.

In decisions about the choice of required course readings, COI may also arise for reasons other than financial interest; for example, the advancement of a professor's academic reputation from the use of their book instead of an alternative or more appropriate text. Interest in one's reputation is perfectly normal and acceptable; the challenge is ensuring that it not unduly influence one's professional duties. Yet, it is extremely difficult to measure the influence that reputation may have on professional behaviour (as compared with financial interests), and thus arrive at a straightforward solution. Instead, discussions about academic integrity are likely to be a more productive means of sensitizing faculty to the diverse interests that may engender COI.

Disclosure is a standard part of the process for dealing with COI, and a means by which universities can promote integrity and transparency. Indeed, both the Waterloo and Montreal COI policies state this at the outset. However, recent psychological research raises important questions about an over-reliance on disclosure mechanisms. First, there is evidence that individuals in a COI are often unable to foresee the extent to which a COI may influence their professional judgement (29); important COI may not be taken seriously and thus go unreported. Second, disclosure may well be insufficient and even lead to further biasing of decisions. Instead of providing the information needed to fairly evaluate an interest, other individuals involved in decision-making and the management of COI may underestimate the extent to which a conflict remains (30).

As often acknowledged in the literature, being in a COI is not in itself unethical if properly managed. It is important to promote a "balancing of valid interests" (31). Such a balance must, however, start with transparency through policy rules that encourage disclosure to enable adequate consensus building and achieve plausible compromise among staff, faculty, students and the university administration. It is not sufficient, as in the case of the Montreal policy, to require disclosure without providing the tools necessary to manage COI when disclosure proves insufficient. Instead, we argue that — as encouraged in the Waterloo policy — more inclusive and transparent discussion, consultation and exploration of suitable arrangements should be promoted to help faculty identify and manage COI.

Procedures

Both the Montreal and Waterloo policies describe the manner in which university staff should proceed to manage or resolve COI. Waterloo's policy states that "any member of the University community with a conflict or potential conflict should seek the counsel and advice of her-his immediate supervisor and disclose the details to that individual" (17). The supervisor will then analyse the situation to determine whether there may be an actual, real or potential COI. The supervisor and the member of the university staff will agree on the alternatives or options to deal with the COI and ultimately determine a course of action. The

agreed upon approach or decision will then be documented. If negotiation does not result in a consensus, the case will be referred upwards through the line of management.

Waterloo does not use a committee process or structure to evaluate COI cases. Rather, the process involves negotiation with the supervisor or director of the unit. This may be criticized as too permissive. Conceivably, supervisors might be in COI with their staff. Also, although supervisors might be well qualified academically and have management experience, they might not have the negotiation skills, training, expertise or familiarity with various cases of COI in order to evaluate the situation and provide appropriate recommendations. The process at Montreal appears to be more direct: more than one person considers the matter and there is a formal appeals committee that reviews all COI that are particularly problematic. Such an institutional process might be even more objective if the committee were completely external to the unit in which a COI has arisen. But as already noted in the case of Waterloo, Montreal COI committees might also suffer from inadequate training or knowledge of how to fairly and effectively assess cases of COI found in their departments. Thus committees may appear to provide effective oversight while in fact falling far short of this goal. To be effective, a committee must not only have knowledge of their particular department to understand the importance of specific external influences in their field of study; they must also have an understanding of the relevant ethical approaches to managing COI.

Availability

To be effective in guiding or regulating faculty, staff or student behaviour, university COI policies must be easily accessible; a policy cannot work if the individuals concerned are unaware of its existence. Common means of disseminating university policies involve: the inclusion of policy information in staff and student handbooks; individual mailing of specific documents; and posting of policies on institutional websites. The obvious limitation of these approaches is their passive nature; there is no incentive for faculty, staff and students — people who are often already very busy with a range of other activities — to *read* the documentation they receive, or to search for such information online. Accessibility of COI policies alone is insufficient for their effective implementation. It is critical to also raise awareness about the importance of COI and the need to follow or adopt practices consistent with the relevant institutional guidelines.

The COI policies of Montreal and Waterloo are both available online at their respective university websites. Montreal's COI policy can be found on the Human Resources webpage (18) and on a page listing all Official University Documents. Waterloo's policy is located on the web pages of the University Secretariat (Policies section) and the Office of Research Ethics (Guidelines & Policies) (17). While both the Montreal and Waterloo documents are easily available (i.e., they are not buried on obscure sub-pages, unlikely to be visited by members of the university community), many other Canadian COI policies are not so readily accessible (16).

Conclusions & Recommendations

In this paper, we examined the different governance approaches, philosophical underpinnings, and styles of two university COI policies: one at the Université de Montreal that is legalistic in form, and the other at the University of Waterloo that is more inspirational. (Table 1 summarizes the key differences and similarities between these two policies.)

Table 1: Comparing Policies

	Université de Montréal	**University of Waterloo**
Style	Highly structured, formal vocabulary	Long sentences & paragraphs, simple vocabulary
Preamble & general philosophy	Staff must avoid COI	Staff must avoid or manage COI
Definitions	No definition	Multiple definitions
Examples	Multiple, simple	Detailed, classic cases
Rules	Simple, formal and rigid: if COI cannot be avoided, then disclose	Complex, disclose COI to head of unit then evaluate if should manage or avoid
Resolution procedures	Bureaucratic committee	Negotiation with unit supervisor
Availability	Easily available through website	Easily available through website

We have not here sought to develop an ideal university COI policy. As mentioned at the outset, the diversity of university institutional cultures and histories will likely undermine the utility of a single, one-size-fits-all, approach to policy development. Some universities may legitimately opt for COI policies that are more or less inspirational or legalistic in style; or they may seek to combine elements of both approaches in a hybrid document that reflects their particular institutional culture. What our comparison offers, we suggest, is a clear description of the strengths and weaknesses of each approach. The following recommendations, some of which may appear to be simple common sense, are our informed opinions following a detailed analysis of 2 COI policies (Montreal and Waterloo), and a more general analysis of policies at 13 Canadian universities (16). These recommendations are intended to inform and guide faculty and administrators involved in the process of drafting or updating university COI policies.

The policy should be concise, as is often the advantage with more legalistic policies such as that of Montreal; a long document is likely to be ignored by busy staff and students. However, to facilitate understanding and uptake, ***the policy should be readable*** and avoid stilted legalistic vocabulary that is often opaque to even an educated audience. Instead, simple and clear language, such as that found in the Waterloo policy, would facilitate understanding of the key issues and procedures. ***The preamble is an important starting point*** in building such an understanding, as it underlines the main values and goals of the policy. It is essential to state clearly, as does the Waterloo policy, why it is important to abide by such a policy. This approach can contribute to further dialogue and consensus building with regards to the appropriate management of COI.

A clear definition of COI is essential. It must be relevant and current; clear and comprehensive enough to apply and encompass potential, apparent, and actual COI; and able to distinguish conflicts of commitment. ***Examples are also important*** as they add a more practical or grounded understanding of the various types of COI that may arise within the diversity that is the university setting. ***Rules about how to manage COI must be clear and concise***. It is important to remember that more rigid and formal rules-based regimes can present real problems in their practical application; as in the case of the Montreal policy, a focus on prohibiting or avoiding COI may entail that unavoidable or manageable COI end up being hidden, thus defeating the purpose of the policy. The management of COI on a case-by-case basis may offer a better way of raising issues and fostering greater consensus among the staff and the university. Nevertheless, certain types of COI, i.e., significant financial interests or institutional COI, may be best dealt with through formal or legalistic guidelines

that provide little room for interpretation; it is an open question, though, whether these issues should be treated through separate specific policies, or as part of general university COI policies.

The procedures for resolving COI must ensure impartiality. The individual or committee who evaluates all disclosures must not be involved with the COI. If the resources are available, an external review committee would be optimal. However, there is an important caveat: the review committee must also have the necessary negotiation skills, training, expertise and familiarity with various cases of COI in order to properly assess the situation. In our (Williams-Jones') experience with various committees, such expertise is invariably lacking, and the process is essentially bureaucratic. Finally, ***the policy should be accessible to all members of the university community*** through, at a minimum, posting on a prominent page of the main university website (e.g., on Human Resources and Research web pages). Furthermore, when new faculty or staff are hired, they should receive information about COI (including the university policy) as part of their orientation packages. Without such accessibility, policies cannot be expected to guide behaviour or have any useful impact on the management of COI.

A COI policy is a necessary component to promoting ethical behaviour, but it is far from sufficient (29). It is therefore essential that members of institutions not only be educated about the content of various policies, but that administrators help foster an ethical culture within which COI policies are acknowledged, debated, understood and ultimately respected. As in the business environment, compliance with a policy can be promoted by a culture of ethics (32). We thus suggest that 'good' COI policies are a fundamental element to promoting transparency and integrity, and enabling the development of a culture of ethics that is sufficiently robust to manage the growing number of COI situations occurring in the university environment.

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Appendix 1: Université de Montréal

Université de Montréal — Official Guidelines, Policies and Procedures

Number: 10.23 CONFLICT OF INTEREST REGULATION

Adoption (French version) 1993-06-01 CU-361-9; 2009-11-24 CU-557-6.2

PREAMBLE

Any member of the University's staff may be placed in a conflict of interest situation in the course of their duties or in the course of external activities, as may any undergraduate student involved in research projects, any graduate student and any postdoctoral fellow.

In order to demonstrate transparency and integrity while respecting university autonomy, the Université de Montréal has decided to adopt regulations to prevent situations of conflict of interest and, where applicable, to protect both individuals and the institution. These regulations require all staff members, undergraduate students involved in research projects, graduate students and postdoctoral fellows to declare any activities likely to place them in real, potential or apparent situations of conflict of interest. This regulation also sets out the procedures for processing these declarations.

Article 1 SCOPE OF APPLICATION

These regulations apply to

1.1 Teaching and non-teaching staff.
1.2 Undergraduate students taking part in research projects, graduate students and postdoctoral fellows

Article 2 RULES

2.1 All members of staff of the University, undergraduate students involved in research projects, graduate students and postdoctoral fellows must avoid placing themselves in a situation where they may have to choose between their personal interests, pecuniary or otherwise, and the interests of the University.

2.2 All members of teaching staff, undergraduate students involved in research projects, graduate students and postdoctoral fellows are required to disclose any actual, potential or apparent conflict of interest to the committee set up for this purpose, so that appropriate measures can be taken to safeguard the University's interests.

2.3 All members of non-teaching staff have an obligation to disclose any actual, potential or apparent conflict of interest to the head of the unit so that appropriate measures can be taken to safeguard the interests of the University.

2.4 Any member of staff, undergraduate student involved in research projects, graduate student or postdoctoral fellow who considers himself or herself to be in a conflict of interest with a member of the unit committee or the head of the unit, as the case may be, may disclose any actual, potential or apparent conflict of interest directly to the Appeals Committee so that appropriate action can be taken to safeguard the University's interests.

Article 3 CONFLICT OF INTEREST

3.1 Without restricting the general scope of these regulations, a conflict of interest arises in particular when a member of staff, an undergraduate student involved in research projects, a graduate student or a postdoctoral fellow:

a) has a direct or indirect pecuniary or other interest in an outside company that deals or is likely to deal with the University;
b) enters into a contract with an outside company in which it has a direct or indirect pecuniary or other interest;
c) directs his or her research activities at the University in such a way as to meet the needs of an outside company in which he or she has a direct or indirect pecuniary or other interest;
d) carries out teaching or research activities on behalf of an external company without regard to the rights of the University;
e) engages in professional or other activities which, because of the time they require, are likely to compromise the performance of their duties at the University or which are likely to compete with the University's activities;
f) accepts a gift or benefit of any kind from an outside company that does business with the University;
g) uses for personal purposes or for the benefit of a third party the resources of the University or the time which, according to the definition of their task, they must devote to it;
h) uses the name of the University, its symbols or emblems, or the names of its associations or organisations for personal purposes;
i) participates in the hiring or promotion, at the University, of a member of his or her family or other persons with whom he or she is related;
j) uses, for personal purposes or for the benefit of a third party, information of a confidential nature that they have acquired in the course of their duties at the University.

Article 4 DISCLOSURE PROCEDURES

4.1 Each year, on a date determined by the person responsible for applying the regulations, members of staff, graduate students and postdoctoral fellows must complete the form provided for this purpose and disclose, where applicable, any actual, potential or apparent conflict of interest situation that may concern them.

When they begin to participate in a research project, undergraduate students must complete the form provided for this purpose and disclose, where appropriate, any actual, potential or apparent conflict of interest situation that may concern them.

4.2 During the course of the year, members of staff, undergraduate students involved in research projects, graduate students and postdoctoral fellows must complete a new declaration if a conflict of interest arises that was not foreseen at the time of their declaration.

4.3 Depending on the case, the forms shall be submitted to the line manager or the Appeals Committee within the prescribed time limits.

Article 5 DEALING WITH DISCLOSURES

5.1 Teaching staff, undergraduate students involved in research projects, graduate students and postdoctoral fellows

Unity Committee

Each non-departmental faculty, department, school, institute and research centre sets up a committee made up of the head of the unit, who chairs the committee, and two professors appointed by a meeting of the unit for a three-year term. The committee is assisted by a graduate student when dealing with the files of undergraduate students involved in research projects, graduate students and postdoctoral fellows. The student is appointed in accordance with the Act respecting the accreditation and financing of students' associations (R.S.Q. A-3.01).

This committee deals with declarations from teaching staff and undergraduate students involved in research projects, graduate students and postdoctoral fellows in the unit.

5.2 Non-teaching staff

The head of each unit processes the declarations of the staff for whom he/she is responsible; he/she informs the Compliance Officer of the measures taken to resolve conflicts of interest.

Article 6 APPEALS COMMITTEE

6.1 The Appeals Committee shall consist of five members, including at least one member of non-teaching staff. The University Council and the University Assembly shall each appoint two members for a three-year term. They shall appoint a fifth member who shall chair the Committee.

6.2 This Committee shall rule on cases submitted to it in writing within 30 days of the decision of the Unit Committee or the head of the unit, as the case may be.

6.3 This committee also receives, in the first instance, declarations from any member, any undergraduate student involved in research projects, any graduate student and any postdoctoral fellow who considers that they are in conflict of interest with a member of the unit committee or the head of the unit, as the case may be.

6.4 This Committee may also propose, proprio motu, ways of resolving conflicts of interest and, to this end, it may obtain any information concerning the measures taken to resolve these conflicts and any relevant information.

Article 7 APPLICATION OF THE RULES

7.1 The Rector, or the Vice-Rector designated by the Rector, shall be responsible for the application of these regulations. The person responsible, in consultation with the Appeals Committee, shall report to the University Assembly and the University Council three years after its implementation and shall propose any amendments to the regulations.

Article 8 COMING INTO FORCE

8.1 These regulations come into force on the day following their adoption by the University Assembly and the University Council.

Appendix 2: University of Waterloo

Policy 69 — Conflict of Interest

Established: April 2, 1991

I. PREAMBLE

A conflict of interest [1], or a potential conflict of interest, exists when a member of the University is or may be in a position to use research, knowledge, authority or influence for personal or family gain or to benefit others to the detriment of the institution.

II. GENERAL PHILOSOPHY AND PROCEDURES

The University acknowledges a commitment, as part of its overall mandate, to transfer knowledge, discoveries and technology to society for its benefit. Interaction of members of the University with external entities is desirable and encouraged when the activity is beneficial to the professional standing of the individual, the reputation of the University or provides a community or professional service. Whatever the nature of the external activities or relationships, the University expects each of its members — faculty, staff, student or officer — to act in a manner consistent with a high standard of integrity and ethical behavior. Accordingly, the University of Waterloo obligates its members and officers acting on its behalf to avoid ethical, legal, financial or other conflicts of interest which may impede or compromise their University responsibilities or the mission of the institution.

This policy is meant to protect both the individual and the institution. Its fundamental tenet is that members should, of their own volition, take the initiative in disclosing conflicts or potential conflict of interest situations. The mere existence of a conflict or a potential conflict does not necessarily imply that the activity concerned should cease. Indeed, conflicts may cover a broad spectrum from those that are minor and easily controlled to those whose consequences could be very serious. There are situations sufficiently complex that judgments may differ as to whether a conflict exists. Accordingly, any member of the University community with a conflict or potential conflict should seek the counsel and advice of her/his immediate supervisor and disclose the details to that individual. A disclosure form (see next page) is available for this purpose.

The immediate supervisor (in consultation with her/his supervisor, when appropriate) will determine whether a conflict, real or potential, exists. In the event that a conflict exists or will exist, the immediate supervisor and the member will agree on a course of action to monitor or avoid the conflict, after which written documentation of the agreement will be held by both the member and her/his immediate supervisor. In the event that agreement cannot be reached, the case will be referred through the appropriate line management channels for resolution, up to and including the Vice-President, Academic & Provost, if necessary.

It is assumed that those with academic or employment supervisory authority who detect what they believe to be violations of this policy will act promptly to provide or initiate the appropriate remedial or disciplinary measures as set out in other University policies, procedures and agreements (including 18, 33, 36, 62, 71 and the Memorandum of Agreement).

III. EXAMPLES

The following list of examples, while not comprehensive, is illustrative of situations which may lead to an indirect or direct conflict of interest:

Favoring of Outside Interests for Personal Gain:

- Entering into a research contract with a company in which the faculty or staff member, or a member of her/his immediate family, has a financial or other interest.
- Directing the faculty member's government sponsored research program to serve the research or development needs of a private firm in which the faculty member has a financial or other interest.
- Influencing the purchase of equipment or materials for the University from a company in which the faculty or staff member has a financial or other interest.
- Accepting significant gifts or special favors for personal gain from private organizations with which the University does business.
- Entering into a licensing agreement for the development of intellectual property, generated as a result of University research, with a company in which the faculty or staff member has a financial or other interest.

Inappropriate Use of University Personnel, Resources or Assets:

- When a supervising faculty or staff member uses University students or staff on University time to carry out work on her/his own behalf for a company in which he/she has a financial or other interest.
- Unauthorized and non-reimbursed use of University resources or facilities to benefit a private concern in which the faculty or staff member has a financial or other interest.

Inappropriate Use of Information:

- Using for personal gain, or other unauthorized purposes, privileged information acquired as a result of the faculty or staff member's University-supported activities; such information might include knowledge of forthcoming developments requiring contractor or sub-contractor selection, bulk purchases, etc.
- Unreasonably delaying publication of research results (e.g., thesis research) or premature announcement of research results to secure personal gain.

Conflict of Commitment:

- Undertaking external consulting, professional or other activities which, by virtue of their time commitment, prevent the faculty or staff member from fulfilling her/his obligations to the University.
- Involvement in external organizations which bring a faculty or staff member into a position of divided loyalty between the mission of the University and the interests of the external organization.

Inappropriate Involvement in Appointment Processes:

- Participating in the appointment, promotion or hiring of a person with whom the faculty or staff member has a marital, familial or sexual relationship.

DISCLOSURE FORMS

[Disclosure forms are available on the web and/or from the Secretariat.]

BACKGROUND RE: DEVELOPMENT OF GUIDELINES AND PROCEDURES ON CONFLICT OF INTEREST

Preamble

The potential for conflict of interest has always existed in university communities because of the diverse interactions of faculty, staff and graduate students with external organizations. However, the increasing complexity of society and the changing role of universities in that society, the multiplicity of interuniversity, university-industry and university-community relations have created a new awareness of the need for guidelines concerning conflict of interest. Few will argue that while the basic mandate of universities — education, research and scholarship, and public service — remains, each institution is struggling to define its own distinctive role and to cope with the reality of a new financial environment. Rapid developments in science and technology over the past two decades, and the realization that transfer of technology from universities to the private sector can contribute significantly to international competitiveness, have generated pressures and financial incentives to engage in cooperative research ventures, consulting or external business relationships. More than ever before, faculty, staff, graduate students and administrators are being asked to engage in a diverse range of economic development activities which carry the potential for conflict of interest. Unless such conflicts are identified and monitored, the very essence of the university mission may be compromised.

Defining Conflict of Interest

Conflicts of interest may be individual or institutional. An individual conflict can be defined as any external activity or undertaking which places an individual in a position which:

A. influences University research, education or business for personal gain, or

B. interferes with or prevents the discharge of her/his University responsibilities, as defined by the individual's employment contract; this is, in reality, a conflict of commitment.

The overall thrust of this definition is that the best interests of the University may be compromised to the personal benefit of the individual employee.

Individual conflicts of interest often derive directly or indirectly from opportunities to participate in externally funded research and in a subsequent interplay between the results of the research and a faculty member's personal or financial interests. Such situations frequently place faculty and staff members in a position to manage contracts, select equipment and supplies, involve graduate students in sponsored research or play administrative roles which demand the utmost in integrity and honesty. Even the appearance of an apparent conflict can have a negative impact on the University and the individual in the eyes of the community.

Institutional conflicts of interest may occur when the University enters into contractual relationships with external bodies, usually private corporations but sometimes government agencies, which bring it into potential conflict with its mandate, with the personal activities of its Board of Governors or even its status as an educational institution. These potential institutional conflicts must be monitored by its governing bodies.

Ethical Principles

In drafting a conflict of interest policy for the University, the Committee was cognizant of both the positive and negative aspects of that part of the University's mission which can be described as "service to society". On the one hand, the University has an implicit obligation to transmit knowledge and the results of research to society for its benefit. On the other hand,

the financial incentives and pressures to contribute to economic and societal well-being have, in the minds of some, distorted University priorities and led to an erosion of autonomy and independence. In this changing environment, it is of paramount importance that the institution have in place a code of ethics which obligates its faculty, staff, students and officers acting on its behalf to avoid ethical, financial or legal conflicts which prejudice the best interests of the University. Thus, a policy on conflict of interest should be an integral component of an entire matrix of policies on ethical behavior in general at the University of Waterloo.

Policy Type

Clearly, defining the entire spectrum of potential conflict of interest situations, both individual and institutional, would be a daunting task. Furthermore, the generation of an exhaustive list of restrictions designed to eradicate conflicts would most certainly compromise the ability of the University to create an environment conducive to the discovery and dissemination of knowledge, the search for truth and understanding, the quality of life and the needs of society. The Committee became convinced that the best interests of the institution would not be served by a restrictive "do not" policy. Such a rigid approach would run counter to the freedom to innovate and the spirit of entrepreneurship which have characterized the University of Waterloo throughout its brief history. Accordingly, the Committee opted for the disclosure route in defining a conflict of interest policy.

Identifying Potential Conflict Situations

One of the keys to any conflict of interest policy relying on disclosure is the ability of individual employees in the institution to recognize possible conflict of interest situations so that they can, in good faith, be recorded and managed. The Committee felt that it would be very useful to provide a list of situations which may be of concern in order to alert employees to potential problem areas. This list can be found in the "Examples" section of the policy on Conflict of Interest.

[1] Statements pertaining to conflict of interest situations are contained in other UW policies, including: 33 (Ethical Behaviour); 40, 44, 45, 48, 50 and 68 (re Academic Administrators); 41 (Contract Research); 49 (Extra-University Activity); 52 (Private Corporations); 62 (Conflict of Interest in Employment & Supervision of Personnel); 66 (Use of University Resources and Affiliation); 77 (Tenure and Promotion).

Conflict of interest policies at Canadian universities and medical schools: some lessons from the AMSA PharmFree Scorecard

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Original version: Mathieu G, Smith E, Potvin M-J, Williams-Jones B. Conflict of interest policies at Canadian universities and medical schools: some lessons from the AMSA PharmFree Scorecard. BioéthiqueOnline. 2012;1(13).

Abstract

Launched in 2007, the American Medical Students Association (AMSA) PharmFree Scorecard is an annual ranking of conflict of interest (COI) policies at American medical centres; it focuses on COIs that may occur when medical education seems likely to be influenced by university-industry relationships, especially those with the pharmaceutical and medical device industries. The PharmFree Scorecard has proven influential in stimulating changes in policy regarding the management of COI at American medical institutions, thus it provides a useful jumping off point for reflection on how and why medical education institutions in other countries — and for our purposes, Canada — should pay more attention to the appropriate identification and management of COI. The PharmFree Scorecard methodology examines a diversity of factors and interests that could influence medical education; as such, it is an interesting approach to analysing the COI policies of medical schools. To test its utility or applicability outside the US, we decided to apply the PharmFree Scorecard to the COI policies of the 16 Canadian universities hosting medical schools. Overall, Canadian institutions rank very poorly, especially in ensuring that education and training tools are provided to staff, students and faculty members to enable the identification and management of COI. However, differences between the US and Canadian medical education contexts, e.g., with regards to the governance and funding of universities, limit to some extent the direct applicability of the AMSA ranking. Canadian medical schools — and their host universities — nonetheless have much to learn from insights provided by the AMSA PharmFree Scorecard ranking, although they can and should go further in developing their own COI policies and procedures.

Acknowledgements

The authors would like to thank Chris MacDonald for helpful remarks on drafts of this paper, the editors Zubin Master and Charles Marsan and the external reviewers for their thorough and constructive evaluations. Many of the ideas here have benefited from ongoing critique and discussion with the Conflict-of-Interest Research Group at the Université de Montréal. Mathieu was supported by a scholarship from the Centre interuniversitaire de recherche sur la science et la technologie (CIRST); Smith was supported by Masters and Doctoral Fellowships from the Social Sciences and Humanities Research Council of Canada (SSHRC) and a J.A. DeSève Scholarship from the Université de Montréal; Potvin was supported by scholarships from the Centre de recherche en éthique de l'Université de Montréal (CREUM) and the Faculty of Medecine. This research was supported by grants to Williams-Jones from the Fonds de recherche du Québec — Société et culture (FRQ-SC), and the Ethics Office of Canadian Institutes of Health Research (CIHR).

Introduction

In the biomedical literature, much attention is given to the behaviour of health research and education institutions regarding the disclosure and management of conflicts of interest (COI) (1-3). Of particular concern is the growing and problematic influence (i.e., creating bias) of the pharmaceutical and medical device industries in physician training, clinical practice and research (4,5). As a result, medical schools and professional associations in North America and Europe have developed policies to address financial COI (6-9) and these have become the subject of much scholarly analysis (2,10-12). In 2009, the Institute of Medicine (IOM) issued an exhaustive report examining the many issues raised by COI in medical research, education and clinical practice. The IOM propose a simple yet effective definition of COI: "A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest" (8).

The American Medical Students Association (AMSA) PharmFree Scorecard is an important example of the attention being given to financial COI (13). Essentially, the Scorecard evaluates the COI policies of US medical schools, mainly scrutinizing their interaction with the pharmaceutical industry. In recent years, the Scorecard has played a significant role in sensitizing US medical education institutions to the issue of financial COI, and to the need to adopt, enforce and make transparent and available their institutional COI policies (14). Curious about the possibility of extending this approach to evaluations of non-US institutional COI policies, we decided to apply the AMSA ranking methodology to Canadian medical schools. It turns out, however, that for the most part Canadian medical schools do not have their own COI policies because they are governed by the policies of their host universities, so we applied the AMSA method to these more general university COI policies. While one might argue that the AMSA method should only be applied to medical faculty COI — because of specific concerns related to pharmaceutical and medical device involvement in medical education — we decided that more general university policies would probably have the same essential content as those policies developed by and pertinent for medical schools. Medical schools share a common commitment towards both education and research, so while pharmaceutical and device industries may be involved in medical education, they are also major sponsors of medical research involving clinician-researchers and students in both the clinical and research settings.

Interestingly, the 16 Canadian university COI policies that we examined ranked very poorly according to the AMSA Scorecard. An analysis of these findings allowed us to identify important limitations with the AMSA method as it relates to evaluating the robustness of COI policies and procedures. Of particular concern is the Scorecard's focus on *financial* COI and the use of *disclosure* as the primary mechanism for the management of unavoidable COI. Specifically, the Scorecard grades disclosure as the *most* relevant management strategy for unavoidable COI in the eleven elements or "policy domains" evaluated, while it should, we argue, be the only the *first part* of a comprehensive management strategy. For example, when interacting with industry in the context of research collaborations or student training in industry settings, disclosure is an essential first step in managing the unavoidable COI that arise. Nevertheless, this first COI management step may and often should be followed by other mechanisms to reduce the risks or harms associated with COI (e.g., open discussion). The focus on disclosure shows, we argue, an important conceptual mismatch with standard recommendations in the ethics and policy literature (15,16), where disclosure is recognised to be a necessary but insufficient mechanism for managing COI. Finally, the AMSA Scorecard focuses on COI at the individual level rather than at the institutional level. That is, it does not consider how institutional arrangements (e.g., involvement with start-up companies,

solicitation and acceptance of industry endowments for faculty positions, buildings or programs) may create important COI for the institution.

Despite these limitations, our critical approach to the AMSA Scorecard — and our application of it to Canadian university COI policies — provided important insights regarding areas in need of significant improvement, namely, the need to develop stronger COI policies, make them accessible and ensure *training* and support for faculty, staff and students in the identification and management of COI.

The AMSA Pharmfree Scorecard

Founded in 1950 under the auspices of the American Medical Association, AMSA is the largest independent US association of physicians-in-training. Because medical colleges have "social, moral and ethical obligations of the profession of medicine", AMSA lobbies for the "removal of COI in medicine" and for "evidence-based rather than marketing-based prescribing practices"; its primary concern are the involvement of the pharmaceutical and device industries in clinical education and research (17). To launch its first evaluation in 2007, AMSA developed a comprehensive framework to assess the content of institutional policies. The PharmFree Scorecard grades US medical schools according to their policies regulating relationships between students, faculty members, and the pharmaceutical and device industries. In a context where industry involvement and influence in academia were raising concerns about financial COI, an issue that looked "inevitable" in US medical schools at the time, AMSA sought to bring attention to the problem of COI and to then pressure medical centres to implement strong policies limiting financial COI associated with university-industry relations (14).

Each year since 2007, the AMSA PharmFree Scorecard group invites "all U.S. schools of allopathic and osteopathic medicine" to voluntarily submit their COI policies for assessment (18).[1] Each policy received is anonymized, assessed and then graded by two independent assessors (names and affiliations listed on the AMSA website). The evaluation examines eleven aspects or "policy domains" where COI can arise and should be addressed: limits on gifts and individual financial relationships with industry, receipt of pharmaceutical samples and speakers' fees, purchasing authority, on-site/off-site industrial educational programs and scholarships, and faculty/medical student COI training. Each domain is scored on a three-point scale (0 to 3), for a maximum total score of 33 points for the best policy: 0 points for "Institutions that do not respond to requests for policies or decline to participate"; 1 point for "Policy is absent or unlikely to have a substantial effect on behavior"; 2 points for "Good progress toward model policy" and 3 points for a "Model policy" [18]. AMSA does not define what constitutes a "Model policy", but we can infer that it is one that provides guidance and recommended standards that could become a reference to ensure optimal governance. A letter grade is then assigned based on the final scores: A ≥ 85%, B ≥ 70%, C ≥ 60%, D ≥ 40%, F < 40%, and I = In process. Institutions failing to report or declining to participate in the survey automatically receive an F grade. The methodology and complete results of the PharmFree Scorecard are available online (13).

Of 152 medical schools invited to participate in the 2011-2012 Scorecard, 149 participated; of the 152 schools, 28 schools received an A (18%), 74 (49%) a B, 15 (10%) a C, and 13 (9%) a D, while 9 schools (6%) received an F. Most of the remaining schools were

[1] Most of the medical schools sampled closely follow their host institution's policy (e.g., Dartmouth, Pittsburgh), although some medical schools also have specific policies for addressing COI arising from institutional holdings or investments (e.g., Stanford).

granted “in progress” or “in process” designations due to ongoing policy development. An examination of the rankings over the five-year history of the survey reveals substantial change, particularly in the last two years. Only 14% of schools were ranked A or B in 2007-2008 compared to 67% in 2011-2012. These rankings through time show significant improvements between 2008 and 2012. This is a tremendous increase compared to the 79 (52%) schools that were assigned A and B in 2010-2011, 45 schools (30%) in 2009-2010, 29 (14%) in 2008-2009, and 21 (14%) in 2007-2008. COI has clearly become a central issue in medical administration and education and more US medical schools are recognizing the importance of implementing thorough COI policies (19).

While the 2011-2012 ranking reveals that some US medical schools still need to develop more appropriate policies and regulations regarding their relations with the pharmaceutical and device industries, the change in rankings over the previous five AMSA PharmFree Scorecards shows that there have been major improvements in the development of “model” COI policies.

Methods

From our perspective, the AMSA methodology is a fruitful starting point to evaluate institutional COI policies. Inspired by this methodology, we conducted our own evaluation and ranking of the COI policies of the 16 Canadian universities hosting medical schools. Contrary to the AMSA evaluation that focuses essentially on medical school COI policies, we examined the policies of Canadian academic institutions hosting medical schools, since few medical schools in Canada have independent COI policies. We did not contact institutions directly, but from the Association of Universities and Colleges of Canada (AUCC) website we were able to identify those institutions hosting medical schools and downloaded from their websites the most recent documents referring to COI policies or guidelines. Keywords (in English and French) used to retrieve these policies were: conflict of interest policy + name of institution, governance + name of institution. Very often, COI policies were referred to in other policies (e.g., nepotism policy, solicitation for gifts, statement on consulting policy). These documents were collected between March and September 2010 (Table 1), thus some have probably changed in the intervening years; it should be noted, however, that 9 institutions had revised their policies between 2006 and 2009. We can only speculate to the reasons for such revisions, but they may include increased attention to changing policies and practices at American institutions (including NIH requirements, which affect Canadian researchers with US financing), as well as moves to respond to recommendations from Canadian actors such as the Canadian Institutes of Health Research (13).

Table 1: Canadian Institutional COI Policies and Guidelines

Institution	COI policies/guidelines	Effective Date
Alberta	Conflict of Interest and Commitment and Institutional Conflict	Jun 26, 2009
	Conflict of Interest and Conflict of Commitment Reporting Assessment Procedure	Nov 16, 2009
	Managing Conflict of Interest in employment procedure	Jun 26, 2009
British Columbia	Conflict of Interest and Conflict of Commitment	Mar 2005
Calgary	Conflict of Interest Policy	Sept 1, 1987
Dalhousie	Conflict of Interest	Jun 24, 2002
Laval	Politique sur l’intégrité en recherche et création et sur les conflits d’intérêts	May 20, 2009
Manitoba	Conflict of Interest	Jun 16, 2009
	Gift and Gratuities offered to University employees	Jan 20, 2009

	Nepotism	Jan 27, 2009
McGill	Regulation on Conflict of Interest	Jun 15, 2009
McMaster	Statement on Conflict of Interest in Research	Mar 11, 2009
	Procedures for Inquiries and Hearings regarding Allegations of Misconduct in Research for Faculty, Staff & Post-Doctoral Fellows at McMaster University	Mar 27, 2002
	Code of Conduct for Faculty	Dec 8, 1994
	Academic Integrity Policy	Sept 1, 2008
	Conflict of Interest Guidelines: Undergraduate and Graduate Studies	Feb 14, 2001
	Conflict of Interest Policy for non-academic staff and academic administrators	Mar 27, 2002
	Statement on Consulting Policy and Procedures	Jan 14, 1976
	Distribution of Income from the Sale of Instructional Materials	Mar 16, 1981
	Staff Policy on Consulting and Freelancing	May 20, 1997
Memorial	Conflict of Interest (policy)	Mar 31, 2009
	Solicitation of Gifts Policy	Apr 1, 1987
Montreal	Règlement sur les conflits d'intérêt	Nov 24, 2009
Ottawa	Conflits d'intérêt — Membres du personnel	Oct 20, 2009
Queen's	Conflict of Interest and Conflict of Commitment	Sept 28, 2001
Saskatchewan	Conflict of Interest	Dec 12, 2008
Sherbrooke	Politique, règles et procédures sur l'intégrité en recherche et sur les conflits d'intérêts	May 20, 2006
Toronto	Conflict of Interest — Academic Staff	Jun 22, 1994
	Conflict of Interest — Librarians	Mar 9, 1995
	Provost's Memorandum on Conflict of Interest and close personal relations	n/a*
Western	Conflicts of Interest	Sept 28, 2000

*n/a = non-applicable

Due to the fact that our evaluation was based on those COI policies that were available online in 2010 — i.e., we did not explicitly solicit submissions as in the AMSA scoring — we had to adapt the AMSA scoring to replace their 0 evaluation for "Institutions that do not respond to requests for policies or decline to participate". We thus used the following 3-point scale, which focused on the content of policies:

- 0 points when a policy or guideline was absent or inaccessible, or lacked key policy elements (e.g., lack of COI training);
- 1 point when policy elements were partially treated or treated through another institutional policy (e.g., misconduct activities, no specific restrictions for non-academic activities, nothing specific to financial COI or conflict of commitment, no clear definition of COI, once-a-year disclosure);
- 2 points when policy elements were addressed, but still incomplete (e.g., no designated institutional COI committee, no clear path for disclosure management, no specific limits to gifts or donations, no public disclosure of COI); and
- 3 points when policy elements could be cited as models (e.g., determined % or $ max. in equity holding in line with US federal requirements, disclosure prior to beginning of activity and COI management plan).

We did not conduct a blind review as in the AMSA exercise but instead performed a thorough review of the different institutional policies and guidelines associated with COI issues to extract the most pertinent elements identified according to the AMSA framework; this was followed by a second review of those specific elements used for ranking institutions. A first coder evaluated all of the university COI policies, guidelines or procedures (when available),

and a second coder verified the overall calculation of the first coder, but did not do any independent coding to calculate inter-coder reliability.

Results

Our application of the modified AMSA scoring to the 16 Canadian institutional COI policies produced some startling findings. At first glance, Canadian institutions appear to have very weak policies, as all received D or F grades, with the exception of the University of Sherbrooke, which obtained a C grade (Table 1).

Table 2: Ranking Canadian Universities with the Modified AMSA PharmFree Scorecard

Interest / University	Industry relationships							Education				Grade	
	Gifts	Consult. fees	Speaking	Public / internal disclosure	Samples	Purchasing	Sales rep	On-site training	Off-site training	Industrial scholarships	COI training	%	Rank
Alberta	3	3	2	2	1	1	0	1	1	1	0	45%	D
British Columbia	3	3	3	2	1	1	0	1	1	1	0	48%	D
Calgary	1	1	1	2	1	1	0	1	1	1	0	30%	F
Dalhousie	3	3	2	2	1	1	0	1	1	1	0	45%	D
Laval	3	2	3	2	1	1	0	1	1	1	0	45%	D
Manitoba	3	3	2	2	1	1	0	1	1	1	0	45%	D
McGill	3	3	3	2	1	1	0	1	1	1	0	48%	D
McMaster	3	2	2	2	1	1	0	1	1	1	0	42%	D
Memorial	3	3	2	2	1	1	0	1	1	1	0	45%	D
Montreal	3	3	2	2	1	1	0	1	2	1	0	48%	D
Ottawa	2	3	2	2	1	1	0	1	1	1	0	42%	D
Queen's	2	2	2	2	1	1	0	1	1	1	0	39%	F
Saskatchewan	3	3	2	2	1	1	0	1	1	1	0	45%	D
Sherbrooke	3	3	3	2	1	1	0	1	1	1	2	55%	C
Toronto	3	3	2	2	1	1	0	1	1	1	0	45%	D
Western	2	2	2	2	1	1	0	1	1	1	0	39%	F

In this modified AMSA scoring, Canadian institutions may appear to perform particularly poorly with regards to interaction with industry when dealing with gifts, consulting, speaking, samples, purchasing matters, as those issues were almost non-existent or not available in any of the 16 COI policies. Similarly, policy mechanisms to address the involvement of industry in education or training were typically very weak or non-existent. So in terms of specific guidelines about industry involvement in university education, almost all Canadian policies obtained a grade of 1 out of 3. With regards to the implementation of mechanisms to provide at least minimal training for academic and administrative staff and students about how to deal with COI, all policies received a 0 grade, except for Sherbrooke which obtained 2 out of 3. These dramatic shortcomings in Canadian institutional COI policies may be explained by the fact that the policies did not include all of the policy elements adopted by AMSA (e.g., gifts, consultant services, purchasing authority), or because different COI issues are being addressed in a diversity of policies and procedures (e.g., McMaster). For example, we gave a poor score to policy elements such as gifts, or external consulting services, on-site or off-site training, public disclosure (e.g., on a web site), and industry scholarships because we could not find any references to gifts and donations in the specific COI policy (e.g., Université de Montréal). But that does not mean that such issues are not dealt with in another policy mechanism or through practical guidelines.

In some universities, there are so many policies addressing different aspects of COI (e.g., in policies on intellectual property, academic integrity, nepotism, purchasing guidelines, research ethics) that members of the institution (e.g., professors, researchers, students) may be either overwhelmed, not know which policy is most pertinent, or not even know that these

policies exist. This situation is all the more problematic in the context of medical schools, where some members (e.g., professors, clinician-researchers, students) are based in the university while others are fulltime in affiliated hospital research centres, which may have their own policies or guidelines. So while it may be important to have a cluster of overlapping and cross-referenced policies and guidelines addressing COI (e.g., the University of Manitoba COI policy is cross-referenced with policies or procedures dealing nepotism, research agreements, research ethics, gift and gratuities offered to University employees, responsibilities of academic staff with regard to students), we agree with the AMSA ranking that a central policy should deal with the major elements associated with financial (and non-financial) COI, if it is to be at all practical and relevant to members of the institution. A patchwork from different policies creates a higher risk of incoherence than does a central policy with a coherent framework.

Interactions between US medical schools and the pharmaceutical and medical device industries may date back further than in Canada, in part due to the stimulus provided by the 1980 US Bayh-Dole Act, and thus explain to some extent the significant attention given to managing the financial COI associated with industry involvement in medical education. Nonetheless, over the past 25 years there has been a tremendous increase in university-industry relationships in Canada, the recognition of which has led Canadian institutions to consolidate various policies as well as develop explicit COI policies (see Table 1). When AMSA launched its first survey in 2007, many US medical schools may have been in the same position as Canadian institutions are today. And while the AMSA Scorecard is focused on those COI specifically associated with pharmaceutical and device industry involvement in medical schools, the AMSA exercise became an opportunity for US medical schools (and universities) to consolidate their own practices and policies and implement more robust COI governance mechanisms.

A thorough examination of the Canadian policies reveals that while still imperfect, many also show important strengths. The Canadian COI policies invariably cover a broader range of issues than those used in the AMSA ranking, likely due to the fact that these are university wide policies; that is, while these policies apply to medical schools, they are not focused on the concerns specific to medical schools (e.g., with regards to pharmaceutical or medical device industry involvement in education). For example, some financial COIs, such as receiving royalties for commercializing intellectual property and holding equity in spin-off companies appear not to be taken into account by the AMSA evaluation even though they are obviously a relevant concern for medical schools; the same concerns regarding undue influence of industry interests in medical education and research apply to relations with spin-off companies. Most Canadian and US university policies place restrictions on such financial interests (14); and many non-financial COI are also accounted for in Canadian (and US) university policies (e.g., academic evaluation of faculty member's immediate family, use of the university's name for personal gain, supervision of graduate students when in relation with faculty members' spin-off companies).

There are some issues that certain Canadian COI policies do not address (e.g., thresholds for financial interests requiring disclosure, which are required by NIH regulations[2]); other issues may not be treated uniformly (e.g., disclosure processes); and finally, certain matters are

[2] Financial compensation from sponsors to investigators, or investigators' proprietary interests in a product under study (including stock options) have potential for causing bias and raise serious concerns about the integrity of research. Limiting financial interests or determining a financial threshold, either in the form of a specific monetary value or percentage of equity, may be seen as a safeguard to protect investigators and universities. Nonetheless, in practice it can be very difficult to determine and apply such financial thresholds.

often overlooked (e.g., COI issues related to intellectual property). Canadian university COI policies also ranked very poorly when it came to dealing explicitly with domains such as "purchasing authority", "industry sales representative" and "industrial scholarships". We did, however, find some of these issues addressed through other institutional policies (e.g., dealing with conflict of commitment or scholarships), although it is worth remembering our earlier criticism about having a fragmented approach to managing COI. And while some specific issues addressed in the AMSA ranking (e.g., consulting fees, gifts, industrial financial support to training activities) were absent from Canadian institutional policies, Canadian institutions also dealt with other issues not evaluated by AMSA, such as limits on patent royalties, equity in start-up companies or industry funding of research. The 16 Canadian university policies evaluated in our study come from the most research-intensive institutions, and so it was no surprise that all had relatively comprehensive COI policies and procedures, alongside other relevant institutional policies or guidelines on "research integrity", "conflict of commitment" or "ethical conduct of research" (e.g., University of Manitoba, McMaster University).

Discussion

Our findings correspond with those of a recent Australian study (21) that applied the AMSA methodology and found a lower overall mean score in Australian medical schools when compared to their US counterparts. But that does not mean that Australian or Canadian university COI policies are necessarily worse than those of US institutions or even that Canadian and US policies are comparable in terms of content. There are important limits — but also benefits — of applying the AMSA methodology outside the US context, that must be considered.

A major strength of the AMSA PharmFree Scorecard — and other COI policy comparisons (1,2,22-25) — is that it brings attention to the importance of having effective institutional policies to address COI associated with pharmaceutical and device industry involvement in medical education and professional training. However, while this attention to financial COI is essential and becoming quite widespread in higher education policy, there is a problematic tendency in American and Canadian university COI policies to not (or to inadequately) take into account non-financial COI. The reality is that not all COI are financial in nature — e.g., interests in academic promotion, personal or professor-student relationships (26), or even a particularly strong allegiance to a school of scientific thought (27,28). Policies founded on this limited perspective may not recognize nor address adequately the other types of COI, which may also result in real or apparent loss of objectivity or create bias. Our concern, then, is that the focus of the AMSA Scorecard on financial COI — while legitimate in the context of their focus on university-industry relations — may contribute to the all-too-prevalent notion that *most if not all* problematic interests are financial, and that financial COI are invariably equivalent to fraud (29).

Overall, our study also corroborates findings by Lexchin and colleagues in their study of 74 Canadian academic health science centres, which demonstrates considerable variability in the scope, focus and quality of institutional COI policies (10). It seems likely that most if not all US medical schools are conscious of these other types of COI (non-financial) and their possible impact on objectivity in health sciences research and medical education. AMSA is also sensitive to these issues, stating that: "While not addressed here, academic medical centers should also have robust policies to ensure the integrity of basic and clinical research, including policies to ensure that academic researchers working in collaboration with industry retain full control of study design, data, analysis and writing" (18). Yet, in separating out

non-financial COI, we feel the AMSA methodology misses an important opportunity to bring attention not only to the full diversity of COI, but also to the importance of implementing a variety of appropriate procedures to manage COI. More worrisome, though, is that this strategy may encourage the ever-present perception that it is only financial COI that matter or that could be potentially problematic.

Our study of Canadian institutional COI policies highlighted two important mechanisms for managing COI that are worth further examination: *disclosure* and *training*.

Disclosure

One of the main differences we observed in our study had to do with the manner in which disclosure is addressed in COI policies. The AMSA methodology gives a maximum score to public disclosure of COI (e.g., on a public website). This is likely based on the commonly held belief in the health sciences (12,22,30,31) — and reinforced by the NIH regulations implemented in 2012 for grants and cooperative agreements — that it is essential for all stakeholders involved to publicly disclose *all* real (actual) or potential (perceived) significant financial COI situations (e.g., financial interests over $5,000) (32). But from the AMSA study, we cannot tell how disclosures are managed (monitored) once they are filed because it does not score "COI management guidelines" for the cases where COI are unavoidable.

By contrast, our analysis of Canadian policies found that COI were often managed by internal mechanisms and not always through public disclosure. Many policies relied, for example, on Research Ethics Boards in their institution and affiliated hospitals to be informed of any COI related to clinical research, and empowered these committees to decide which management measures (e.g., requiring disclosure to participants or changes to the recruitments process) were most appropriate to manage the particular COI. Similarly, COI are among the issues covered in the 2010 2nd Edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2) and are addressed in depth in Chapter 7 (33). Because COI can jeopardize the integrity of research and the protection of research participants (and medical education, given the strong link between research and teaching), Canadian institutions are invited to develop appropriate policies, safeguards and procedures. Our review of Canadian COI policies found that some of the TCPS2 recommendations are still not common (e.g., a central mechanism for COI management). And while internal management processes may have some limits (e.g., some institutional COI may not be properly addressed), so too does internal and public disclosure if they are not dealt with appropriately (e.g., misinterpretation and unfounded public mistrust).

It has been shown that the disclosure of unavoidable COI can induce a sense of security on the part of the person disclosing — and for those witnessing the disclosure — that gives an unreasonable sense that the conflict has been resolved; in other words, disclosure may actually induce an unconscious cognitive bias in favour of the person disclosing because disclosure is viewed in a positive manner (34). By contrast, the widespread negative perception of COI means that many people may not disclose even when it is obligatory for fear of the negative view of colleagues, i.e., that being in a COI means that they are unethical (29). So for disclosure to be accepted as an appropriate response, students and researchers who recognise that they may be in an actual or perceived COI must also have a significant degree of confidence in institutional mechanisms, i.e., that in disclosing they will be dealt with fairly (35). While disclosure (either internal or public) can, in many cases, be of utmost importance in managing financial and non-financial COI, it is arguably only one part of a robust and refined management process. Such a process should, we suggest, involve

appropriate and specific institutional guidelines and training to assist faculty members, staff and students in the recognition and management of any COI in which they may actually, apparently or potentially be involved.

Training

The AMSA Scorecard's inclusion of COI training in its evaluation highlights the importance of COI education as a critical mechanism for building awareness and changing how individuals and institutions understand and deal with COI (36). Even with the different academic contexts between the US and Canada, training is still viewed as important. However, all but one Canadian university scored 0 which shows a significant weakness in Canadian COI policies. There are many examples of training tools (e.g., online courses, conferences, workshops) developed by US academic institutions (e.g., Johns Hopkins University (37), the University of Texas Health Science Center at Houston (38), Columbia University (39)) to help students, faculty members, and staff recognize the institutional nature of COI situations, and understand how private interests (either financial or non-financial) can affect judgment, objectivity and public trust.

Aside from the University of Sherbrooke, none of the Canadian universities hosting a medical school appear to have developed tools for helping students, faculty members or administrative staff in identifying and managing COI. This being the case, it will likely be very difficult for faculty, staff and students in these institutions to 1) accurately appreciate when they are in a COI, 2) recognize that such situations may cause potential harms (e.g., loss of objectivity, loss of trust), or 3) understand whose interests are at risk. Without appropriate education for specific COI situations (both financial and non-financial), it will be difficult to create a culture of ethics amongst the members of an institution and ensure compliance with institutional COI (and other ethics) policies. Training and education should be a key element in a COI policy that aims to build awareness and effective monitoring and management of COI (36).

Study Limitations

The application of AMSA Scorecard highlighted the importance of these two aspects, i.e., disclosure and training. However, the method used has important shortcomings that are important to note. First, as mentioned at the outset, the AMSA Scorecard was created to evaluate and rank (and ultimately influence) medical school COI policies as they related to pharmaceutical and medical device industry involvement. Our intention in applying the AMSA Scorecard was to see what items differed between the Canadian university and US medical school contexts, and to reflect on whether different approaches to dealing with COI were warranted. We are, nevertheless, sensitive to the fact that there are a few Canadian medical schools that have (or are in the process of) put in place their own COI policies and which may have more stringent provisions that are specific to and focused on those COIs typically found in medical schools.

With regards to our coding method, it was not blinded because we have been working on these policy documents for quite some time (since 2007) and could identify them simply by their content. Moreover, we did not have a particular interest in determining which Canadian university "won" or performed the best in our study because our objective was not the ranking itself. While the influence of excellent or poor AMSA rankings has been a powerful motivator for US medical schools (and thus a means of influencing change, at least providing a motivation to develop and provide COI policies), we were interested in reflecting on what this ranking system could tell us about the content of Canadian COI policies. Finally, while

the second coder verified the conclusions of the first coder, we decided that independent coding to calculate inter-coder reliability was not necessary. This was decided because the coding method was done in a deductive matter (based on the AMSA Scorecard) and categories are quite precise, thus there is much less space for interpretation than in an inductive study where the coding scheme is established depending on the content analyzed.

Conclusion

A straightforward application of the AMSA PharmFree Scorecard to evaluating the quality of COI policies of medical education institutions outside the US is likely of limited direct utility. The considerations that are so important for the US context, namely the disclosure of financial interests in unavoidable COI and any involvement of the pharmaceutical and medical device industries in medical education, may be less of an issue (though still pertinent) in higher education systems such Canada's, where universities are funded primarily from public sources (e.g., federal and provincial governments). Further, in our study of Canadian universities, we found a variety of policies that were pertinent but not specifically focused on COI (e.g., conflict of commitment, nepotism, academic integrity, intellectual property, research ethics). A more in-depth and comprehensive examination of institutional *approaches* to managing COI would have found that most Canadian universities provided their communities with a diversity of mechanisms to address COI (40). However, while these diverse approaches might support attention to a broader range of COI (including non-financial), their very diversity and lack of coordination can also undermine appropriate COI disclosure and management.

As we have shown in our application of the AMSA Scorecard to 16 Canadian university COI policies, it is essential to 1) reflect on the *utility and limits of disclosure* as a COI management mechanism, and 2) develop and implement *training and educational tools* for students, faculty and administrators so that they are empowered to both identify COI and manage these situations when they cannot be avoided. The AMSA PharmFree Scorecard has clearly played an important role in motivating US medical education institutions to improve their financial COI policies, and more generally, has contributed to on-going international reflections on the need to develop and implement effective COI policies in medical schools and academic institutions more generally. With growing interest and sensitivity on the part of Canadian medical students to issues of COI, we might even see the rise of a "Canadian AMSA" movement, unless Canadian medical schools, universities or other governance bodies work proactively to develop "model policies" and procedures for the institutions.

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Developing a model conflict of interest policy at the Université de Montréal

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Original version: Smith E, Marsan C, Williams-Jones B. Développement d'une politique sur le conflit d'intérêts à l'Université de Montréal. Report submitted to the Groupe de travail sur les conflits d'intérêts de l'Université de Montréal et le Groupe de travail sur la gouvernance du Comité universitaire d'éthique de la recherche de l'Université de Montréal (CUÉR). 29 Jun 2012.

Acknowledgements

This chapter builds on the findings and conclusions of an internal report entitled *Développement d'une politique sur le conflit d'intérêts à l'Université de Montréal*, presented June 29, 2012 to the Groupe de travail sur les conflits d'intérêts de l'Université de Montréal (Conflict-of-Interest Working Group) and the Groupe de travail sur la gouvernance du Comité universitaire d'éthique de la recherche de l'Université de Montréal (Working Group on Governance of the University Committee on Research Ethics). Our work benefited greatly from discussions with these two groups, with members of the Conflict-of-Interest Research Group, and with Sophie Arès in the office of the Vice Principal Human Resources and Planning (VPHRP) at the Université de Montréal. We would like to particularly thank Michel Bergeron, Maude Laliberté, Charles Dupras, Ghislaine Cleret de Langavant, and the two peer-reviewers for their very helpful comments. Smith was supported by a PhD Scholarship from the Social Sciences and Humanities Research Council of Canada (SSHRC). This research was supported by grants to Williams-Jones from the Université de Montréal, the Fonds de recherche du Québec — Société et culture (FRQ-SC), and the Ethics Office of Canadian Institutes of Health Research (CIHR).

Introduction

In both Canada and the United States, government funding agencies have required universities to demonstrate that they have in place institutional conflict of interest (COI) policies, in order to obtain government funding for research projects. Since 1995, the US National Institutes of Health/Public Health Services (NIH/PHS) have required universities seeking US federal funding for biomedical and behavioural research to have a written institutional policy to manage financial COI. In 2011, the scope of the NIH/PHS policy was expanded, and institutions are now required to post on a publicly accessible website, information about the significant financial interests of funded senior or key researchers (1).

The importance of having institutional COI policies has been similarly emphasized at Canadian universities following the introduction of guidelines in 2011 from the three federal funding councils (National Science and Engineering Research Council, NSERC; Canadian Institutes of Health Research, CIHR; Social Sciences and Humanities Research Council, SSHRC). The *Tri-Agency Framework: Responsible Conduct of Research* (TAF) (2) states that researchers who receive funds from the federal funding councils must "appropriately manage any real, potential or perceived conflict of interest in accordance with the institution's policy on conflict of interest in research". This requirement applies to researchers in all fields, including the humanities and social sciences, health sciences, natural sciences and engineering. Further, the 2nd edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2) (3) states that "Institutions shall develop and

implement conflict of interest policies including procedures to identify, eliminate, minimize or otherwise manage conflicts of interest that may affect research." (3) The management of COI has thus become the responsibility of all university researchers and their host institutions. Institutions not conforming with these various guidelines (e.g., lacking appropriate policies and procedures, or permitting unethical practices) are at risk of having *all* federal (and provincial) grant funding frozen or even revoked, until such time that the institution is again in conformity with the guidelines.

Understandably, there has been significant pressure on Canadian research institutions — and specifically universities — to develop or update their COI policies, as well as policies dealing with academic integrity and research ethics (aka responsible conduct of research), more generally (4). Yet, studies of Canadian institutional COI policies have shown great variability in the content, structure and quality of these policies, particularly in comparison with their US counterparts (5-8). It is thus all the more important that new or updated policies aim towards the "state of the art" as presented in the scientific literature and keep up with the "best-practices" in the academic community (9) while accepting diversity based on specific contextual realities. Finally, for a policy to be effective, it must be supported by governance structures (e.g., procedures, guidelines, forms), knowledge transfer initiatives to raise awareness and build stakeholder buy-in, and implemented by the relevant personnel (e.g., staff, administrators, committees) who are then held accountable for their actions.

A number of questions should be addressed when beginning to formulate a new (or update an existing) COI policy: How should COI be defined and identified? Who should declare a COI? What is the best method or process to manage COI? Not surprisingly, university COI policies differ considerably in both content and style (10), and address these questions in different ways. For example, studies have shown that COI policies for clinical research vary widely in determining what types of COI are to be included (e.g., financial, personal, ideological), as well as approaches to managing COI (e.g., collecting disclosure forms, disclosing to research participants, disclosing on publication of research results) (6,11,12).

The effective formulation of university COI policies and procedures is also a complex optimization problem that involves careful consideration of both ethical ideals and institutional realities (administrative structures, other policies, institutional culture). Ideally, policy development would entail a thorough and iterative process of drafting, evaluation, testing and reformulation (13). While this process might be time consuming and costly, it should be a preventative measure and thus a worthy investment. Simply adopting a COI policy that is not properly adapted to the context may seem like a quick-fix solution but does not promote the essence of COI policies which includes the reduction of bias, protection of human participants and public trust in research. In order for a COI policy to be "successful", we argue that it must 1) be accepted by the university's membership, and not simply imposed; and 2) made operational through clear procedures so that challenging COI are (and are seen to be) addressed effectively. Our experience strongly suggests that if these two criteria are not met, then the COI policy is likely to be ignored. Given the varied and numerous disciplines, departments and administrative units that make up a university, the formulation of a COI policy (and its associated procedures) that meets such standards is a significant challenge.

This challenge was taken up by the Conflict-of-Interest Research Group (COIRG) at the Université de Montréal (Quebec, Canada) during the summer of 2012. We had been conducting research on COI policies since 2005, including analyses and critique of the existing institutional policy (10,13). In this chapter, we present an overview of the policy

development process that we adopted, discuss key policy issues that arose during this process and explain our decisions, and then present the final draft that was submitted to the University administration in 2012. For a variety of reasons — primarily concerning the difficulty of modifying top-level policies and changing institutional culture — our draft policy did not go forward. The existing COI policy was slightly modified, and focus was instead placed on improving certain procedures to promote the application of COI management practices. Over the following two years, our group helped develop new procedures (i.e., detailed Application directives) to better operationalize the existing policy, produced an updated declaration form (which included a clear definition of COI) and educational tools to help build awareness about COI amongst the university community. Finally, a series of training sessions were provided to administrators and members of statutory COI committees, in order to begin changing the culture at the institution regarding COI management. A summary of this work will be presented at the end of the chapter.

Despite the fact that our initial draft policy was not implemented by the University, we believe that the research and rationale used to justify our policy are central to effective COI management and can thus serve as examples for other academic institutions seeking to update their policies and procedures. Specifically, our draft policy is innovative because it provides high-level statements that communicate the policy rationale and directives in a manner that is sufficiently general to apply to a diversity of COI situations. We also took an approach of outlining principles and providing related articles in order to address a number of major challenges, i.e., be meaningful to many diverse contextual realities and address both institutional and individual COI. This “aspirational” as compared to “legalistic” approach was also designed to be part of a broader program of education and awareness-raising, to ensure that the policy would be applicable, and part of a process of culture change within the institution.

It should be noted that the draft policy was tailored to meet the particular needs and institutional context of the Université de Montréal, a French-language institution and one of the largest research universities in Canada, with more than 70,000 members, including students, professors, researchers and administrative staff. The draft policy and accompanying procedures (Application directives) were written in French and designed to address the COI situations that occur in a research-intensive institution (see drafts in Annexes 1 & 2). Here, we present an English version of the draft policy, outlined in Boxes, preceded or followed by text briefly explaining the content, structure, and reasoning behind each section. Clearly, other institutions would need to adapt our draft policy (and approach) to meet their own specific concerns and contexts (institutional, national, etc.). So while we do not pretend that our approach to COI governance (draft policy, procedures, etc.) can or should be adopted “as is”, we do believe that the approach we used, as well as the policy’s structure and associated educational resources, can be of use to other institutions.

Initial considerations

From the outset, we took the view that many COI problems occur as a result of misunderstandings or ignorance of existing guidelines and institutional procedures, something that likely stems in part from the implementation of overly complex policies and a lack of awareness-raising activities (14,15). Although it might be the case that certain COI are intentionally ignored out of bad faith or conscious unethical behaviour, this would most likely constitute a minority of cases. In his article on COI in the financial services, Boatright (16) discusses three main obstacles to perfect contracting, or in our case, case policy-making: 1) *complexity*, the inability to regulate in complex situations; 2) *contingency*,

the issue of unforeseen situations; and 3) *uncertainty*, where cases may be foreseen but where one is uncertain how to proceed. While there are many institutional regulations in academic institutions, there remains considerable complexity, contingency and uncertainty, factors that have to be continuously considered in the management of COI.

Another recurring problem identified in the literature is the conviction held by many individuals that they can manage their own COI; consequently, they may choose not to disclose their situation with their peers or superiors. To some extent, this secrecy may be a reaction to the widespread negative connotation attributed to COI situations, such that individuals frequently confuse COI with an avowal of corruption or fraud (17). More specifically, in the health sciences where COI has been closely scrutinised, academics may often think that COI are the result of a morally "bad" decision and so indicate unethical behaviour (18). This negative perception is to a great extent the fallout from highly publicized scandals involving the poor management of COI. For example, the mismanagement of financial COI in university-industry partnerships has shown that private interests can unduly influence research, increase the risk of bias and ultimately cause harm to human participants, exemplified for instance in the Nancy Olivieri and David Healy cases at the University of Toronto (19). The media coverage of these COI situations undermined public confidence in the integrity of research and academic institutions (11).

In drafting our policy, we wanted to make it clear that there is nothing inherently blameworthy about being in a COI if it is properly managed; in fact, sometimes our institutional arrangements make COI probable, if not inevitable (20). The simple fact that industry financially supports research — as is often the case in many clinical trials — can make researchers feel like the study should support the interests of their benefactor to ensure future funding. However, many methods may be used to manage COI, such as a third party replicating the experiments or making long term contracts with industry that are not based on output. Our aim was to produce a policy — as well as associated application directives (e.g., procedures) — that would be both useful and constructive so that COI could be managed instead of demonized or ignored. Specifically, the policy should: 1) help members of the university community better understand the typical situations or conditions in which COI occur; 2) discern the different types and severity of COI; and 3) determine the appropriate responses and mechanisms to mitigate COI (e.g., disclosure, withdrawal or avoidance).

We considered two approaches or styles, each of which has advantages and disadvantages: a *legalistic* format with its concise, rigid structure and technical language; and a more discursive and descriptive approach with an *aspirational* tone, that seeks to inspire or encourage the reader to resolve issues based on principles and a sound ethical culture (10). The Université de Montréal COI policy that is currently in use was implemented in 1993 (updated in 2009). It is written in a legalistic style, and while making for a concise and direct policy, the language is at times hard to understand and tends to be narrowly focused on obligations and prescriptions; this is evident in the title of the current policy, i.e., "Conflict of Interest *Regulations*". Drawing on the strengths of both the legalistic and aspirational styles, we developed a COI policy that would assist individuals in dealing with COI but without focussing only on strict deontological rules. Accordingly, we opted for a fairly concise and non-technical style based on core principles and a set of prescriptive articles that would offer practical guidance and effective solutions. We believed that it was critical to provide a clear and sufficiently complete understanding of COI so that the university community

(e.g., professors, administrators, teaching staff, students), and the university as an institution could meet their ethical obligations.

To avoid creating an overly lengthy and complicated policy, we proposed that the above-mentioned elements be organized into three distinct but interrelated documents: 1) a *central COI policy* (a document that includes principles and normative guidelines), 2) *application directives* (a document outlining COI management procedures), and 3) *educational materials* (examples, training tools). In addition to defining COI and issuing directives, a policy initiative should clearly explain key principles and also provide useful management procedures. The latter should include approaches to avoid COI where possible, and to mitigate COI that occur or are unavoidable. Procedures should also remain as generic as possible to be relevant to the diverse contexts of university teaching, research and administrative management. This chapter will mainly focus on the content of the draft central policy, which was completed in June 2012. But we will also present briefly the other elements necessary for effective COI governance — i.e., application directives (21), administrative structures, and educational materials — that were developed between 2012 and 2014.

As the Université de Montréal is a large institution with many different disciplines and departmental contexts (i.e., humanities, social sciences, applied sciences, engineering, health sciences), we decided that a decentralized structure for COI management was the most feasible and appropriate; this measure was implemented by the University. Conversely, in a smaller institution, other more centralised mechanisms may be considered a better fit. By a decentralised structure, we mean that the management of COI is a local responsibility at the outset, managed at the level of departments or administrative units. Alongside local COI committees, the management of COI could also be integrated within other structures (e.g., in standing committees for scholarship competitions, Departmental Assemblies) and use existing reporting structures (Heads of Department or Unit, Deans, etc.). A central "University COI Management Committee" was created and has overall responsibility for application of the central COI policy, implementation of directives, support of educational activities, and also serves as a venue to hear cases that could not be resolved or managed lower down the administrative chain of responsibility. This central committee also communicates with and provides advice to committees, departments and/or faculties for addressing COI considerations in their own unit-level procedures or guidelines, so that these are in accordance with the central COI policy. This approach combines compliance with a central policy and the flexible application and resolution of COI when and where they arise.

Step One: Definition and Preamble

Looking for an 'ideal' definition

Clearly defining what is meant by a COI is a key element of any COI policy (22); accordingly, we focused considerable attention to drafting a definition that was clear and pertinent to the context of the Université de Montréal. We began by examining the various definitions of COI used in the academic literature, as well as those in university policies and professional codes of ethics. For some scholars, such as Erde (23), COI is interpreted so loosely or broadly that it cannot be defined with sufficient precision or detail to be useful or practically applied. Brody supports Erde's theory when he mentions that "the moral terrain that conflict of interest addresses is wide and varied, so that the concept ought to be seen as a general topographic guide, and not as a precise definition" (22, p.24). When COI is the subject of intellectual or philosophical reflection, a broader interpretation without constraints of

definitional semantics may be desirable. But in the development of a university policy, the scope should be limited to those aspects that are particular to the university context, namely education, research, the valorisation of research and administrative duties. Further, a normative policy that lays out clear guidelines should be sufficiently clear to be understood and applied in all areas of university activity, unless one opts for multiple COI policies to cover these different activities (e.g., for students, for professors, for administrators).

Certain definitions of COI found in the literature are not necessarily appropriate for all academic settings. For example, in a business or public sector context, COI can be defined as "a situation in which a person has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties as, say, a public official, an employee, or a professional" (20, p.58). While this definition is clear, it does not apply, for example, to a student who is neither an employee nor a professional. Also, it does not speak to the risk involved in the COI situation. Such risk can include bias in research, harm to a research participant, or threat to the reputation of a member of the university (e.g., student, professor, administrator) or to the university as a whole. This search for definitions of COI led us to examine and compare other Canadian university COI policies. Our initial observation was that the interests of the institution were often the central concern and those of its members were either minimised or simply ignored. If members do not understand what COI is, and the associated issues or consequences to themselves — as well as to the institution — of unmanaged COI, then they may be vulnerable to engaging in inappropriate or unethical behaviour. We wanted our draft policy to enable the institution and its members, both individually and collectively, to understand the benefits of effectively managing COI situations.

A COI definition that is better aligned to the Canadian university research context can be found in the aforementioned TCPS2 (3).

> A conflict of interest may arise when activities or situations place an individual or institution in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. These interests include, but are not limited to, business, commercial or financial interests pertaining to the institution and/or the individual, their family members, friends, or their former, current or prospective professional associates (3).

Since the latter is the central document governing Canadian research ethics in the university context, we used its definition of COI as a starting point. However, because the TCPS2 applies primarily to research involving human participants, we needed to broaden the definition so that it could apply to all university members involved in research (regardless of whether this included human participants or animals), teaching and administration. We thus replaced the term "research" with "the duties or responsibilities related to their status or function." This broader formulation recognizes that while university members — e.g., students, researchers, professors, teaching assistants, research assistants, professionals, administrative staff — have a great deal of liberty to pursue their interests, they also have wide variety of duties and responsibilities, and as such, the types of COI they face may be very different.

In addition, to avoid confusion and to simplify the definition, we removed reference to "real, potential and apparent" COI as these terms give rise to misunderstanding and controversy in the literature. For example, some authors have argued that potential COI can become real without an individual necessarily being aware so the difference between potential and real

COI becomes blurred in practice (24). Moreover, while seemingly less serious than a real COI, an apparent COI can be equally damaging to a person's or to an institution's reputation, due to the loss of confidence associated with even "only apparent" COI.

As for the latter part of the TCPS2 definition, we were concerned that examples of conflicting interests would be deemed by the reader to be complete and so lead to a "check list" approach to understanding and managing COI; that is, only those examples listed would be considered problematic, and situations not listed would not be perceived to be COI. We looked to the literature for other types of interests that might conflict with university members' duties or responsibilities and so included interests that are political, religious or ideological (25,26). We were nonetheless cognisant of the importance of having more detailed examples, and so planned to present and discuss various examples of COI and their management methods in the documentation accompanying the central policy, i.e., the procedures, guidelines, and educational resources.

Finally, we wanted to emphasize from the outset — in the definition itself — the risks and practical consequences that members may experience if they do not manage COI; accountability for risk management of COI is also addressed in the formulation of the core principles of the policy. We had considered using the notion of lack of objectivity as a key risk, but for many scholars — particularly in the social sciences and humanities — 'objectivity' is often linked to a contested positivistic vision of science. Bourdieu, for example, maintains that we must acknowledge that we are influenced by our own interests; denying such influences only buries them in our subconscious, so reflexivity is essential (27). We should reflect on our own interests in our social context (family and work) in order to understand the reasons that motivate or influence our judgments or decisions. In the draft COI policy, we wanted to promote self-reflection and awareness as a key element, so that members of the university might better identify COI that arise in their particular contexts. Identification is an essential first step prior to evaluating the extent to which certain interests may pose a risk to the integrity of research, education or administrative duties.

We proposed the following definition of COI (English translation):

> A conflict of interest may arise when, in the course of activities, the interests of an individual or institution conflict with the interests inherent in the duties and responsibilities associated with their status or functions. These interests include business, financial, ideological, religious or political interests relating to the institution and/or the individual, family members, friends or business associates, whether past, present or future. These conflicts create the risk of altering a member's judgment and may consequently have an adverse effect on the trust (of the public and members of the university) toward the institution and its members.

Developing a Preamble

Generally, a preamble introduces the goals and philosophy that underpin core policy statements. Inspired by the structure of the TCPS2, we decided to present general principles in the preamble that were relevant to the university context, and then include operational principles in the main body of the policy. Both sets of principles are interrelated and aim to promote an ethical approach in implementing future COI management procedures. Setting principles and guidelines within an organizational context is a means to encourage members to seek common values (28).

Unquestionably, COI can be detrimental to the university as an institution, and this must be addressed. Accordingly, we decided to retain the principle of protecting impartiality, and by extension credibility and reputation, but to apply it more generally to individual members,

to the university, and to the conduct of education and research. Acting transparently was also identified as an important principle in the management of COI situations, something that is widely acknowledged in the literature and in other policies that regulate COI (e.g., TCPS2). The application of this principle, however, presents some interesting challenges. While we agreed that there should be a transparent process to handle COI cases (also recommended in the TCPS2), we were not convinced that it would be appropriate to follow the NIH approach of requiring public disclosure in cases of significant financial COI (1). Further, as explained by Cain, Loewenstein and Moore (29,30), empirical research shows that those who are party to disclosures (e.g., members of a committee, the general public) may have trouble discounting advice from potentially biased sources in COI situations. An individual disclosing a COI may think that the public discounts their research more than is actually the case, and may even exaggerate results to get their point across, thus creating more bias. Others might feel that disclosure provides something of a "moral license", whereby there is less of a requirement or responsibility to monitor and assess their own interests and possible COI since they have already done their duty through disclosure. A reliance on disclosure as the only or primary mechanism for managing COI may thus be inappropriate, as clearly stated by the editors of PLoS, "Does Conflict of Interest Disclosure Worsen Bias?" (31). Critical of the COI disclosures of 70% of the authors who contributed to the Diagnostic and Statistical Manual of Mental Disorders (DSM), the editors affirm that "the overemphasis and reliance on disclosure policies is exactly what leaves the real problem of conflict of interest unaddressed." (31)

Confronted with the limitations of disclosure, we reflected on other ways to deal with COI in the university. In the preamble, we stated that a situation must be disclosed at the outset to a committee or superior that has knowledge of how to manage such situations. As noted by Chugh, Bazerman, and Banaji (24), an individual alone may have difficulty assessing their COI, and the various risks and harms that may arise. When people are too close to a situation, they may underestimate or refuse to acknowledge (willingly or unconsciously) various influences; as a result, their judgment will be more subjective and sometimes biased. When individuals start discussing their COI with their peers or superiors, this opens the discussion to other insights and different perspectives that may ultimately be helpful in COI management, promoting more impartial research which is a central responsibility in science. To facilitate discussing COIs, the institution should provide training and support to enable individuals to understand and identify COI and then assume responsibility for its management. As such, we decided that the responsibility of the university and of its members for managing COI should be introduced at the outset of the policy, namely in the Preamble.

Preamble (proposed)
To carry out its mission of teaching, research and administrative duties, the Université de Montréal as an institution and its individual members are responsible for managing their conflicts of interest (COI). COI are situations where private interests of a member (or their relatives and associates) and the duties and responsibilities related to their status or function conflict. In a COI situation, there is a risk that the private interests of the member of the institution may undermine the exercise of their responsibilities or those of the institution.

Considering the wide variety of actors who attend and work for the University, as well as the diversity of responsibilities and obligations tied to their role or status, the management of COI is rather complex. While it is expected that members and the institution have interests other than those related to the academic mission, all must do a self-analysis to determine whether those interests could influence their judgment and their decision-making. COI, or the mere appearance of COI, may threaten the confidence of third parties and therefore the reputation of the university

and its members. However, it should be mentioned that some COI are unavoidable but this does not necessarily imply that the member of the institution lacks integrity. The complexity of these situations requires learning how to identify and assess COI situations or the appearance of COI, to ensure their proper management in the best interests of the members and the institution.

The aim of this policy, in addition to managing COI, is to prevent the harm associated with COI situations such as: bias in research, favouritism or inequity in education, questionable administrative practices and loss of trust in members and/or in the institution. The goal of COI management is 1) to ensure that decisions or judgments of members of the institution are as objective as possible and meet the standards of academic integrity, 2) to safeguard the credibility and trust in the institution and its members (from the public and from members of the institution), and also more generally in research, teaching and university administration.

The academic institution is financed largely through public funds. It is therefore important to maintain the public's confidence in the community and in the university. Thanks to the public's trust in the university, and the resulting funding, researchers can work with great independence and enjoy academic freedom. Excellence in research and education enables the transmission of new knowledge to future generations, while the proper administration of the University allows for sound and fair management of the institution. To the extent that members are responsible for meeting their obligations related to their role or function, university activities and mission will be protected. However, confidence in the University is only possible if the institution has the proper tools to minimise risk of harm to others, to research and to education due to unmanaged COI. Failure to manage a COI can hinder an important obligation to your role as member of the University, and in the long run, undermine academic liberty and the social role of the University.

Consequently, it is necessary to protect the institution and its members with good COI management tools, in order to ensure the protection of academic activities, the reputation of the university and its members who contribute to research, teaching, and administration, and maintain the mission of the University.

The Université de Montréal expects all its members to use their best judgment to promote excellence in research, education and university administrative practices. Good judgement involves making assumptions based on inductive and/or deductive facts obtained in as a disinterested manner as possible. While exercising perfectly objective and impartial judgment is impossible in practice, this policy seeks to promote it in principle. A preferred way to achieve this goal is by promoting solidarity and collaboration among colleagues who together create a fair environment for teaching, administrative management, and research that meets the criteria and established methods in their discipline or field of study. Any undue influence (not related to the responsibility of the member, unit, Faculty, committee, or the institution itself) — whether financial, political, ideological, familial or spousal in nature (current, past or future) — may impair objectivity and impartiality of the members of the institution and must therefore be identified, evaluated, and when the situation requires, prevented or managed.

Step Two: The Principles at Work

Following the development of the Preamble, we discussed the formulation of the policy itself, including its format and content. Consistent with the approach adopted in the TCPS2 (3), the proposed policy consists of seven normative principles (with descriptions) that are articulated via twelve directive articles. This approach provides an accessible transition from theory (principles) to practice (articles) with sufficient explanation for the reader to understand the rationale behind each principle and article. It was our view that University members are more likely to accept and adopt rules and procedures that are understandable, coherent and justifiable. The articles would then be further explained, and their implementation supported through guidelines and training tools.

The following principles and articles form the core of the draft COI policy and come immediately after the *Preamble* and *Definition*.

Responsibilities and obligations of academic members
All University members have written or implied obligations and responsibilities related to their function or status. As well, the University and the various Faculties and units must honour their respective institutional responsibilities to ensure an environment conducive to education, administration and research that demonstrates excellence and integrity. One of the responsibilities of members of the University and its various units and Faculties is to follow institutional rules regarding research ethics, scientific integrity and university management.

Article 1: All University members must recognize the responsibilities associated with their status and function, the first being to follow institutional rules, which includes the COI Policy.

*Article 2: University members must recognize the risks of all types of influence (economic, political, ideological, family or partnership, etc.) that may conflict with their responsibilities and impair their objectivity and impartiality. T*hese conflicts must be identified, evaluated, and when the situation requires, prevented or managed.

Transparency
It is essential to ensure that policies and procedures used by the University be transparent and accessible. The simple fact of disclosing one's COI to one's superior or colleagues can also be considered as transparency, especially when accompanied by institutional procedures that support fair and equitable management of COI. Depending on the situation and the level of risk of the COI, the University member should disclose their COI to a colleague, manager or the University COI Management Committee as defined in the application directives. Also, the management of certain COI may require declaration to various actors, such as Research Ethics Boards.

Article 3: The COI policy and application directives should be transparent to the public.

Article 4: The COI policy, its application directives and any local COI procedures must be accessible to all individuals to whom they apply, that is to say, to members of the institution. These members must sign a document attesting that they have read the materials.

Article 5: When a COI is identified, it becomes mandatory to disclose its existence to a recognized entity in order to begin the process of COI evaluation and management within a reasonable period of time.

Article 6: Following the evaluation of a COI, the act of disclosure of the interests to various actors such as students, colleagues or the public may be necessary (and in some cases be sufficient to manage the COI).

Shared responsibility and decentralization of COI management
COI are often caused by situations or contexts in which the institution or individual members are placed. Thus, the responsibility to identify, evaluate and manage COI must be shared by the University, its units, Faculties and members. Although there is one central COI policy at the Université de Montréal, members will manage COI with their superiors in their respective work contexts. Thus, the different units, Faculties, departments and services are often best placed to create and implement various procedures to ensure the identification, evaluation and management of COI. Such entities can consider a COI to be high-risk because of elevated risk for human participants or to the reputation of the individual or the institution. A University COI Management Committee will be responsible for managing these high-risk cases while also hearing appeals that cannot be managed by the units, as well as cases of institutional COI. The Committee will also

have the responsibility of ensuring the proper interpretation of the application directives related to this policy.

Article 7: Academic or administrative units shall develop procedures to enable the identification, evaluation and management of COI, considering the particularities inherent to their duties and responsibilities within the institution.

Article 8: The University COI Management Committee has the responsibility to handle particularly high-risk cases of COI, hear appeals cases that cannot be managed by the units, and cases of institutional COI. The committee must also ensure the proper interpretation of the application directives related to this policy.

Solidarity in the identification, evaluation and management of COI

When people are too close to a situation, they may either underestimate the COI or simply be unaware of its existence. In other words, without a certain level of detachment from the situation, judgment can become more subjective and objective analysis is difficult. In these cases, the assistance of your superior/colleague/another third party is often necessary to evaluate the COI in a more objective manner. In practice, academic members are asked to disclose the situation and then, in collaboration with a supervisor or colleague, evaluate the conflict(s) to find an appropriate management method. In order to understand and evaluate the influences of conflicting interests, questions must be asked. COI management will be much more effective and beneficial to university members if they take an active role in finding a management strategy that is appropriate to the circumstances and level of risk involved.

Article 9: In general, the management of COI will be achieved through collaboration between the supervisor/colleague and member of the university in the COI. In high-risk situations, the management of COI can include the University COI Management Committee. This collaboration between various parties is essential in facilitating the analysis of the risk involved in the COI situation.

Protection of the reputation of individuals and the institution

Poorly managed COI can have negative effects such as harm to research participants, or lack of objectivity or impartiality of administrators, professors and researchers. These risks can affect scientific research, management of administrative or student records, procurement services or education as a whole. COI situations may not only damage the reputation of the University member involved but may also taint that of the University as an institution as well as scholarship more generally. Research and education are much more beneficial to society if the population has confidence in the methods used by administrators, educators and researchers. The very suggestion or hint of a lack of integrity (as with the appearance of COI) can damage the image of the University and its members. It is essential that the institution and its members act at all times to promote the excellent reputation of the Université de Montréal and its members by ensuring the support and confidence of its members and the public. Therefore, even where there is an appearance of a COI, the members and the institution will identify, assess and manage the situation so as not to damage the reputation of the members or the institution.

Article 10: To maintain an excellent reputation, the University and its members must try to prevent situations that give the appearance of COI. The identification, assessment and management of the appearance of COI should take into consideration the risks of these situations.

Prevention and education

All members of the institution (including those who make decisions on behalf of the institution) should be able to identify a COI. The evaluation and management of COI should be done by the individual's direct superior who should have a good knowledge of how to deal with COI, including

its identification, evaluation and management. The University COI Management Committee at the Université de Montréal should create training tools (educational material, courses, e-learning, etc.) necessary to ensure continuous learning.

> *Article 11: The University COI Management Committee, in collaboration with Faculties and units, has a responsibility to provide ongoing training on COI to all members of the institution, and to ensure that the policy is clearly understood and that the procedures are interpreted and applied appropriately.*

Consequences of not respecting the COI Policy
All members of the University must respect the COI Policy. If after benefiting from the necessary resources (policies, educational materials) to identify and manage COI, a member still fails to state their COI or does not properly manage the situation (by the standards of this policy), consequences and sanctions will be considered and applied as deemed necessary. A member who is in COI should, whenever possible, demonstrate a willingness to solve the conflict at hand.

> *Article 12: Every University member should declare their COI related to their status or function. Neglecting to declare a COI or failure to manage a COI can lead to consequences and sanctions determined by the employment agreement of the member and the University COI Management Committee.*

Step Three: From Policy to Procedures

As is the case for many Canadian university COI policies, the existing policy at the Université de Montréal defines the management of COI as one activity (usually mitigation of risk through disclosure) and incorporates procedures into the main policy. Our draft policy — presented above in English (French version in Annex 1) — employed a more comprehensive COI management framework, consisting of three different steps: identification, evaluation and management. The principles and associated articles refer to procedures that would then be presented in greater detail in the procedures for different university members (e.g., students, researchers, administrators/staff) (draft Application directives, French version in Annex 2).

As mentioned frequently in the literature, it is unrealistic to expect policies to settle or address all COI (32). Application directives and guidelines are essential for outlining examples and procedures that are most applicable to particular cases, in order to best identify, evaluate and manage COI situations in various contexts. Investment is also necessary to make the policy enforceable and operational so that management processes, mechanisms and structures (e.g., committees) work effectively. This requires significant investment (financial, personal) if education and prevention are considered as part of policy implementation, as they should be. In the long term, this investment would hopefully foster a culture of ethical management of COI and responsible conduct, and so safeguard the reputation of the university members and the institution.

As noted in the Introduction, our draft policy was approved by both Working Groups but failed to be implemented by the University. Nonetheless, with the close collaboration of the University Administration, it was possible to develop more robust system of COI governance. Between 2012 and 2014, the COIRG worked with the VP Human Resources and Development to build new Application directives (21), as well as guidelines and procedures that reflected the spirit of our draft policy but were also in conformity with the COI policy in effect at the University. The decentralized management structure already in place (but under-used) at the University was re-enforced, with specific guidelines (e.g., management

plan) for departmental or unit-level COI committees (33). The annual COI declaration form was completely re-written, beginning with our proposed definition of COI, and structured around focused questions to help individuals reflect on their interests so that the local COI committees could better evaluate these declarations (34). A 75min training session was developed, video-recorded and given on 6 occasions in the spring of 2013 to more than 300 University personnel (departmental/unit secretaries, directors, etc.), and then became part of an annual training offered to new employees (35). Finally, all of this information was compiled in a comprehensive website to provide a diversity of resources (written, video) to help the University community understand COI (definitions, examples) and how they are to be managed appropriately (procedures for different members, forms, guidelines).

Conclusion

The opportunity to draft a new COI policy for the Université de Montréal enabled the COIRG to put into practice its collective academic experience and analytic expertise in critiquing COI policies and management processes. This hands-on assignment gave us valuable insights into the practical limitations associated with the recommendations presented in the academic literature regarding COI management. We decided to move beyond a role of simply critiquing COI policy to one of developing and promoting a new model for COI governance. The failure of our draft policy to be implemented was certainly disappointing and pointed to the importance of both attempting such an endeavour and also recognizing the limits of what one can do when the institutional environment is not conducive to policy change. Despite this policy "failure", our close collaboration with and support from the VP Human Resources and Planning enabled us to be active participants in starting to change the institutional culture, although more work is still necessary to truly change behaviour of university members regarding the ethical management of COIs. We were encouraged to develop and deploy what we believe to be a cutting-edge approach to building awareness about how to identify, evaluate and manage COI in a university context. This experience also stimulated our interest in building specific procedures to manage COI in different contexts, for example, in the constitution of masters and doctoral juries (36). Our hope is that this presentation of a draft COI policy, and the approach we used to develop it and the subsequent procedures and resources at the Université de Montréal, can serve as a model for other researchers and institutions seeking to improve their COI governance mechanisms and build an institutional culture where COI can be discussed, evaluated and managed appropriately.

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Annexe 1 : Projet non approuvé de Politique de l'Université de Montréal sur les conflits d'intérêts

Préambule

Pour mener à bien sa mission d'enseignement, de recherche et de saine gestion administrative, l'Université de Montréal en tant qu'entité institutionnelle ainsi que ses membres individuels doivent être responsables de la gestion de leurs conflits d'intérêts (CI), c'est-à-dire les situations qui engendrent un conflit entre les intérêts privés d'un membre (ou de ses proches et associés) et les devoirs et responsabilités liés à son statut ou sa fonction. Une telle situation entraîne un risque que les intérêts privés du membre portent atteinte à l'exercice de ses responsabilités ou celles de l'institution.

Considérant la grande variété des acteurs qui travaillent pour l'université, ainsi que la diversité des responsabilités et obligations propres à leurs fonctions ou statuts, la gestion des conflits d'intérêts s'avère assez complexe. Même s'il est attendu que les membres et l'institution elle-même ont des intérêts autres que ceux liés à la mission universitaire, tous doivent faire une autoévaluation visant à vérifier si ces intérêts pourraient influencer leurs jugements et leur prise de décision. Le conflit d'intérêts, ou la simple apparence de conflit d'intérêts peut nuire à la confiance de tiers et donc à la réputation de l'institution universitaire et de ses membres. Cependant, il faut mentionner que certains conflits d'intérêts sont parfois inévitables et cela ne veut aucunement dire que les membres ou l'institution manquent d'intégrité. La complexité de ces conditions requiert d'apprendre à identifier et évaluer les situations de conflits d'intérêts ou d'apparence de conflit d'intérêts, afin d'assurer leur bonne gestion dans le meilleur intérêt des membres et de l'institution.

La visée de cette politique aspire, en plus de gérer les conflits d'intérêts, à prévenir les torts liés à des situations telles que, notamment : les biais dans la recherche, le favoritisme ou les injustices dans l'éducation, la gestion administrative douteuse et la perte de la réputation des membres ou de l'institution. La gestion des conflits d'intérêts a donc comme but 1) d'assurer que les décisions ou les jugements des membres et ceux de l'institution soient les plus objectifs possibles et répondent aux normes d'intégrité académique ; 2) de sauvegarder la crédibilité et la confiance dans l'institution et en ses membres (de la part du public et les membres de l'institution), mais aussi, plus généralement, dans la recherche, l'enseignement et l'administration universitaires.

L'institution universitaire est financée en grande partie grâce à des fonds publics. Il est ainsi essentiel de maintenir la confiance du public dans la communauté et l'institution universitaire. En faisant valoir la confiance du public et des fonds qui en découlent, les chercheurs peuvent aujourd'hui travailler de façon autonome et jouir d'une véritable liberté académique. D'ailleurs, un enseignement de qualité permet de propager de nouveaux savoirs aux prochaines générations et la bonne administration de l'université permet la gestion saine de l'institution. Dans la mesure où les membres demeurent responsables de leurs obligations liées à leur statut ou leur fonction, toutes les activités universitaires se trouvent protégées. La confiance dans l'institution universitaire n'est possible et souhaitable que si elle est exempte du risque de porter atteinte à autrui, à la science, à l'enseignement en raison de conflits d'intérêts. Négliger de gérer un conflit d'intérêts peut porter atteinte à une obligation et ainsi, à long terme, porter atteinte à la liberté académique.

Conséquemment, il est nécessaire de doter l'institution de bons outils de gestion des conflits d'intérêts, dans le but de garantir la protection des activités universitaires et de la réputation

de l'institution et de tous ses membres contribuant de près ou de loin à la recherche, l'enseignement, la gestion administrative et la valorisation des activités universitaires.

L'Université de Montréal s'attend à ce que tous ses membres utilisent leur bon jugement, afin de promouvoir l'excellence de la recherche, de l'enseignement et de la saine gestion des affaires universitaires. Avoir un bon jugement implique de faire des présomptions inductives ou déductives basées sur des faits obtenus de manière désintéressée. Bien que l'exercice du jugement objectif et impartial absolu soit en pratique impossible, la présente politique aspire tout de même à en promouvoir le principe. Une voie privilégiée pour atteindre cet objectif est la solidarité entre collègues, confrères et consœurs qui font la promotion neutre et équitable de l'enseignement, de la gestion administrative et de la recherche en respectant les méthodes établies dans leurs disciplines et champs d'action. Toute influence indue, non liée à la responsabilité du membre, d'une unité, d'une faculté, d'un comité ou de l'établissement lui-même, telle que les influences économiques, politiques, idéologiques, familiales ou provenant de partenaires (actuels, passés ou futurs) peut nuire à l'objectivité et à l'impartialité des membres ou de l'institution, et doivent ainsi être identifiées, évaluées et, lorsque la situation l'exige, évitées ou gérées.

Définition d'un conflit d'intérêts

Un conflit d'intérêts peut survenir lorsque des activités ou des situations placent un individu ou une institution en présence d'intérêts (personnels, institutionnels ou autres) tels qu'ils entrent en conflit avec les intérêts inhérents aux devoirs et responsabilités liés à son statut ou sa fonction. Ces intérêts comprennent notamment des intérêts commerciaux, financiers, religieux, politiques ou idéologiques se rapportant à l'institution ou l'individu, les membres de sa famille, ses amis, ou ses associés professionnels, qu'ils soient anciens, actuels ou futurs. Ces conflits risquent d'altérer l'intégrité des décisions prises et ainsi causer des torts et compromettre la confiance du public et des membres de l'Université envers l'institution et ses membres.

Les responsabilités et obligations des membres universitaires

Les membres universitaires ont tous des obligations et des responsabilités, que celles-ci soient écrites ou tacites, liées à leur fonction et leur statut. Pareillement, l'établissement universitaire ainsi que ses diverses unités et facultés doivent honorer leurs responsabilités, afin d'assurer un milieu d'enseignement, de gestion et de recherche qui fait preuve d'excellence et d'intégrité. L'une des responsabilités des membres de l'institution universitaire et de ses différentes unités et facultés est de suivre les règles institutionnelles en matière d'éthique de la recherche, d'intégrité scientifique et de gestion administrative, notamment.

> ***Article 1 :*** *Tout membre universitaire doit reconnaître les responsabilités liées à son statut et sa fonction, la première étant de suivre les règles institutionnelles, ce qui inclue la Politique de gestion des CI.*
>
> ***Article 2 :*** *Les membres universitaires doivent reconnaître les risques de toutes influences (économique, politique, idéologique, familiale ou de partenariat) pouvant entrer en conflit avec leurs responsabilités et nuire à leur objectivité et leur impartialité. Ces conflits doivent être identifiés, évalués et, lorsque la situation l'exige, évités ou gérés.*

La transparence

Il est essentiel de s'assurer que la politique et les procédures utilisées par l'Université soient transparentes. Le simple fait de déclarer ses CI à un supérieur ou à des collègues peut être

considéré comme de la transparence, surtout lorsqu'il est accompagné de procédures institutionnelles de soutien justes et équitables qui prennent au sérieux la gestion des CI. Selon la situation de CI et du niveau de risque encouru, le membre et l'instance appropriée, telle que définie dans les procédures, peuvent déclarer le CI à un collègue, à son directeur ou au Comité universitaire de la gestion des CI. De plus, la gestion de certains CI peut se réaliser par la déclaration du CI à différents acteurs, tels que les étudiants (enseignement), les collègues ou le public (publications).

> ***Article 3 :*** *Cette politique et les directives d'application qui en découlent doivent être transparentes aux yeux du public.*
>
> ***Article 4 :*** *La politique et les directives d'application ainsi que toute procédure locale sur les CI doivent être accessibles à tous les individus auxquels elles s'appliquent, c'est-à-dire aux membres de l'institution. Ces derniers doivent signer un document qui atteste qu'ils ont pris connaissance des textes.*
>
> ***Article 5 :*** *Suite à l'identification d'un CI, il devient obligatoire de le déclarer à une entité reconnue, puis d'entamer un processus d'évaluation et de gestion du CI dans un laps de temps raisonnable.*
>
> ***Article 6 :*** *Suite à l'évaluation d'un CI, le geste de divulgation du conflit aux acteurs, tels que les étudiants, les collègues ou le public peut s'avérer nécessaire (et être suffisant dans certains cas pour en faire une bonne gestion).*

Le partage des responsabilités et décentralisation de la gestion des CI

Les CI sont souvent causés par des situations ou des contextes dans lesquels se trouvent placés des individus ou l'institution. Ainsi, la responsabilité d'identifier, d'évaluer et de gérer les CI doit être partagée par l'Université, les unités, les facultés et les membres. Bien que cette politique soit centrale à l'Université de Montréal, la gestion de la plupart des CI sera réalisée par les membres avec leurs supérieurs dans le contexte du travail de chaque individu. Ainsi, les différentes unités, facultés, départements et services seront souvent les mieux placés pour créer et implanter diverses procédures en mesure de permettre l'identification, l'évaluation et la gestion des CI. Un Comité universitaire de gestion des conflits d'intérêts aura la responsabilité de gérer les cas à risque particulièrement élevé, les cas d'appels qui ne peuvent être gérés par les unités et les cas de CI institutionnels. Ce même comité aura aussi comme responsabilité de s'assurer d'une bonne interprétation des normes d'applications liées à cette politique.

> ***Article 7 :*** *Toute unité académique ou administrative doit développer des procédures visant à permettre l'identification, l'évaluation et la gestion des CI, en considérant les particularités inhérentes à leurs fonctions et responsabilités au sein de l'institution.*
>
> ***Article 8 :*** *Le Comité universitaire de gestion des conflits d'intérêts a la responsabilité de gérer les cas à risque particulièrement élevé, les cas d'appels qui ne peuvent être gérés par les unités et les cas de CI institutionnels. Le comité doit aussi s'assurer de la bonne interprétation et application des normes liées à cette politique.*

La solidarité pour aider l'identification, l'évaluation et la gestion des CI

Lorsque des individus se trouvent trop proches d'une situation, cela peut faire en sorte de sous-estimer les CI ou de les rendre inconscients. En d'autres mots, sans une certaine distance en regard d'une situation, notre jugement peut devenir plus subjectif. Dans ces cas, l'aide d'un cadre ou d'un collègue (ou une autre tierce partie) devient souvent nécessaire pour

évaluer le CI objectivement. En pratique, les membres universitaires sont invités à énoncer la situation pour ensuite, en collaboration avec un supérieur ou collègue, évaluer le(s) conflit(s), afin de trouver une méthode de gestion appropriée. Dans le but de bien comprendre et d'évaluer les influences des intérêts en conflit, des questions doivent être posées. La gestion des CI sera beaucoup plus efficace et profitable aux membres universitaires, s'ils peuvent prendre un rôle actif pour trouver une stratégie de gestion qui soit appropriée aux circonstances et au niveau de risque en jeu.

> ***Article 9 :*** *De façon générale, la gestion des CI se réalisera en collaboration entre les membres universitaires et leurs collègues ou supérieurs. Cette collaboration est essentielle pour initier un échange qui puisse permettre de mieux comprendre les influences des CI ainsi que les risques potentiels qui pourraient leur être imputés.*

La protection de la réputation des individus et de l'institution

Un CI mal géré peut avoir des impacts néfastes, tels qu'un tort aux participants à la recherche, un manque d'objectivité ou d'impartialité des administrateurs, chercheurs et professeurs. À long terme, ces manques peuvent porter atteinte à la recherche scientifique, à la gestion des dossiers administratifs ou étudiants, aux services d'approvisionnement ou à l'enseignement dans son ensemble. Les situations de CI risquent non seulement de nuire à la réputation du membre universitaire touché, mais aussi à celle de l'Université en tant qu'institution ainsi qu'à l'érudition de manière plus large. La recherche et la formation s'avèrent beaucoup plus profitables pour la société si la population a confiance dans les méthodes utilisées par les administrateurs, chercheurs et enseignants. L'apparence même d'un manque d'intégrité (comme l'apparence d'un CI) peut nuire à l'image de l'Université et de ses membres. Il est donc primordial que l'institution et tous ses membres fassent en sorte d'agir en tout temps dans le but de promouvoir l'excellente réputation de l'Université de Montréal en assurant l'appui et la confiance de ses membres et du public. Partant, même les situations où il y a apparence de CI doivent être considérées (identifiées, évaluées et gérées) pour ne pas nuire à la réputation des membres ni de l'institution.

> ***Article 10 :*** *Afin de préserver une excellente réputation, l'Université et ses membres doivent tenter de prévenir les situations qui donnent l'apparence de CI. L'identification, l'évaluation et la gestion de l'apparence des CI se feront en considération des risques encourus par ces situations.*

La prévention et l'éducation

Tous les membres de l'institution (ce qui inclut ceux et celles qui prennent les décisions au nom de l'institution) devraient connaître ce que sont les CI, afin d'être en mesure de les identifier en temps et lieu. L'évaluation et la gestion des CI seront entreprises au moyen d'un cadre qui devrait, *a fortiori,* avoir une bonne connaissance des CI, de leur identification, de leur évaluation et de leur gestion. Le *Comité universitaire de gestion des conflits d'intérêts de l'Université de Montréal* devra ainsi créer des outils de formation (matériel pédagogique, cours, etc.) nécessaires pour assurer cet apprentissage.

> ***Article 11 :*** *Le Comité universitaire de gestion des conflits d'intérêts, en collaboration avec les unités et facultés, a la responsabilité d'assurer une formation continue sur les CI pour tous les membres de l'institution et d'assurer que la politique soit clairement interprétée et que les procédures soient bien assimilées et conformément appliquées.*

Conséquences de ne pas respecter la PCI

La politique sur les CI doit être respectée par tous les membres universitaires; or, après avoir diffusé et promu les ressources mises en place pour contrer les CI, le fait qu'un membre omette de déclarer ses CI ou les déclare sans faire en sorte de gérer adéquatement la situation (selon les normes de la présente politique) peut amener des conséquences et même l'application de sanctions. Le membre qui se trouve en CI doit, dans la mesure du possible, démontrer une volonté de résoudre le(s) conflit(s) dans le(s) quel(s) il se trouve.

> ***Article 12*** *: Tout membre universitaire doit déclarer les CI qui le concernent en lien avec son statut ou sa fonction. La négligence de déclarer un CI ou la persistance et la non-résolution d'un CI pourraient amener des conséquences et des sanctions déterminées par la convention d'emploi du membre ou le Conseil universitaire sur la gestion des CI.*

Annexe 2 : Projet non approuvé de Directives d'application pour la gestion des conflits d'intérêts

Les procédures suivantes ont été mises en place, afin de permettre aux membres universitaires de gérer leurs conflits d'intérêts par un processus simple et pratique. La mise en œuvre de la Politique sur les CI de l'Université de Montréal sera assurée grâce à la mise sur pied d'un Comité universitaire de gestion des conflits d'intérêts (CUGCI) ayant pour mandat d'aider les unités et les départements à intégrer les présentes procédures. Ce Comité compte des experts en matière d'intégrité et de CI, mais aussi des experts juridiques ainsi que différents membres de l'Université (professeurs, étudiants, etc.) Bien que ce Comité se préoccupe de l'application de la Politique sur les CI, il ne prétend pas être en mesure de gérer tous les conflits d'intérêts existants dans une université. La gestion des CI à l'Université de Montréal se fera de manière le plus souvent décentralisée, sauf dans les cas à risques élevés. Afin d'aider les membres à gérer les cas particuliers de CI et promouvoir les meilleures pratiques, des formations sur les CI seront offertes aux membres de l'Université.

Les responsabilités et obligations des membres universitaires

Article 1 : *Tout membre universitaire doit reconnaître les responsabilités liées à son statut et sa fonction, la première étant de suivre les règles institutionnelles, ce qui inclut la Politique de gestion des CI.*

- Une fois par année, tous les membres de la communauté universitaire doivent lire la politique sur les CI, et signer le formulaire en ligne (dans leur portail de l'UdeM) qui confirme qu'ils ont lu et compris la politique; ce procédé pourrait aussi être utilisé pour d'autres politiques. Nous souhaitons ainsi informer les membres des principaux règlements de l'Université et assurer un processus de responsabilisation individuelle.
- Cette procédure devrait également être jointe à un rappel des ressources disponibles (textes, site web, formation) visant à mieux comprendre la problématique des CI.

Article 2 : *Les membres universitaires doivent reconnaître les risques de toutes les influences (économique, politique, idéologique, familiale ou de partenariat) pouvant entrer en conflit avec leurs responsabilités et nuire à leur objectivité et leur impartialité. Ces conflits doivent être identifiés, évalués et, lorsque la situation l'exige, évités ou gérés.*

- Discuter avec les étudiants et les collègues des contextes ou situations qui sont en mesure d'affecter l'impartialité ou de donner une impression de partialité en raison de CI.
- Intégrer dans les possibilités d'apprentissage (études de cas, présentations, textes).

La transparence

Article 3 : *Cette politique et les directives d'application qui en découlent doivent être transparentes aux yeux du public.*

- Les politiques et procédures de gestion des CI seront disponibles sur le site de l'Université, par exemple, dans la page de recherche, la page sur la gouvernance / page des politiques. Par des liens sur d'autres pages (ex., CÉR, SGPUM, etc.)
- Les documents seront à la fois accessibles (disponibles, faciles à trouver) et faciles à lire (lorsqu'un langage technique sera utilisé, des explications seront données dans un glossaire); soutenus par wiki et d'autres informations explicatives.
- Présentation de liens vers d'autres ressources et outils de formation (ex., interviews d'experts qui parlent de CI sous forme de capsules vidéo).

Article 4 : *La politique et les directives d'application ainsi que toutes les procédures locales sur les CI doivent être accessibles à tous les individus auxquels elles s'appliquent, c'est-à-dire aux membres de l'institution. Ces derniers doivent signer un document qui atteste qu'ils ont pris connaissance des textes.*

- Sur le site web de l'UdeM, mais aussi dans le matériel d'admission pour les étudiants, le personnel et les professeurs qui se joignent à l'institution.
- Discussion des CI et des procédures avec les nouveaux membres lors de l'admission.

Article 5 : *Suite à l'identification d'un CI, il devient obligatoire de le déclarer à une entité reconnue, puis d'entamer un processus d'évaluation et de gestion du CI dans un laps de temps raisonnable.*

- Lorsqu'un individu identifie ou est préoccupé par un CI dans lequel il peut être impliqué, il doit contacter un collègue ou son autorité sénior (directeur, directeur) pour lui dire.
- Dans le contexte d'un comité, il est nécessaire de déclarer le CI au comité et de discuter des procédures de gestion appropriées (ex., la récusation, la déclaration, etc.)
- Il est nécessaire de documenter les processus d'analyse, d'évaluation et de gestion des CI utilisées.

Article 6 : *Suite à l'évaluation d'un CI, le geste de divulgation du conflit aux acteurs, tels que les étudiants, les collègues ou le public peut s'avérer nécessaire (et être suffisant dans certains cas pour en faire une bonne gestion).*

- Déterminer le processus de déclaration approprié qui sera requis; probablement basé sur le risque potentiel ou apparent.
- Encourager la discussion avec les collègues, les supérieurs, les parties prenantes concernées par le processus.
- Déterminer comment et où la déclaration peut et doit être faite, par exemple, en personne, devant une classe, dans un projet de recherche, à son département / unité ou sur le site web institutionnel.
- Suite à toute divulgation, faire un retour en arrière pour consulter la Politique et les procédures, de sorte qu'elle fasse partie d'un processus transparent (c'est-à-dire qui vise à montrer comment les CI sont gérés).

Le partage des responsabilités et décentralisation de la gestion des CI

Article 7 : *Toute unité académique ou administrative doit développer des procédures visant à permettre l'identification, l'évaluation et la gestion des CI, en considérant les particularités inhérentes à leurs fonctions et responsabilités au sein de l'institution.*

- En collaboration avec le Comité universitaire sur les CI, les unités ou départements ont le devoir d'examiner les politiques et les procédures mises en place pour leurs enseignants et chercheurs, afin 1) d'identifier les cas où il y a (ou pourrait y avoir) des CI récurrents, et 2) d'intégrer les principes clés de la Politique centrale dans leurs politiques et procédures.
- Les membres seront invités à travailler sur des cas typiques de CI représentant des exemples significatifs qui permettront de mettre en place certaines des meilleures pratiques. Ces dernières pourront à leur tour inspirer les unités / départements dans le développement de leurs propres politiques et procédures (ex. les modèles de formulaires de consentement éclairé qu'on trouve dans les pages Web des CÉR).
- Les unités ou départements devront produire un rapport annuel décrivant les mesures adoptées pour intégrer la notion de CI dans les politiques et les pratiques locales, et aussi comment les cas de CI ont été traités (nombre, nature, etc.)

Article 8 : *Le Comité universitaire de gestion des conflits d'intérêts a la responsabilité de gérer les cas à risque particulièrement élevé, les cas d'appels qui ne peuvent être gérés par les unités et les cas de CI institutionnels. Le comité doit aussi s'assurer de la bonne interprétation et application des normes liées à cette politique.*

- L'objectif est d'identifier une procédure de travail fondée sur l'évaluation des risques, afin de déterminer les seuils de risque qui permettent qu'un CI soit traitable localement.
- Les unités ou départements doivent travailler avec le Comité universitaire, afin d'établir des procédures permettant d'identifier les circonstances nécessaires pour qu'une affaire oblige de passer dans la *chaîne hiérarchique* jusqu'au Comité universitaire.
    - Par exemple, un CI impliquant le directeur de l'unité / département, ou une procédure d'évaluation locale gênante parce que le CI est soit très sensible ou particulièrement compliqué.
    - Examiner les cas qui peuvent mener à une inconduite.

La solidarité pour aider l'identification, l'évaluation et la gestion des IC

Article 9 : *De façon générale, la gestion des CI se réalisera en collaboration entre les membres universitaires et leurs collègues ou supérieurs. Cette collaboration est essentielle pour initier un échange qui puisse permettre de mieux comprendre les influences des CI ainsi que les risques potentiels qui pourraient leur être imputés.*

- Le point de départ sera la discussion avec les collègues et les autres parties impliquées dans la situation ou qui sont susceptibles d'en être affectées.
- Reconnaître le fait que de se trouver dans une situation de CI ne veut pas dire que la personne est mauvaise ou immorale, mais que la situation peut créer un biais ou un risque de partialité. C'est l'une des premières étapes de la gestion appropriée des CI.

La protection de la réputation des individus et de l'institution

Article 10 : *Afin de préserver une excellente réputation, l'Université et ses membres doivent tenter de prévenir les situations qui donnent l'apparence de CI. L'identification, l'évaluation et la gestion de l'apparence des CI se feront en considération des risques encourus par ces situations.*

- Dans la visée d'un effort important pour identifier et gérer les CI au sein de l'ensemble des membres de l'institution universitaire, cette Politique nécessite un engagement à tous les niveaux (du statut d'étudiant en passant par le personnel, les professeurs, les chercheurs et les administrateurs) afin de préserver la réputation des individus et de la communauté universitaire.
- Si un membre externe ou interne pouvait avoir des raisons légitimes de croire qu'un membre universitaire est dans un CI, il peut y avoir une apparence de CI, voire même un CI réel. Pour sauvegarder la réputation des individus et des membres, il est important de déclarer les CI à un cadre, même s'ils ne sont que des apparents.

La prévention et l'éducation

Article 11 : *Le Comité universitaire de gestion des conflits d'intérêts, en collaboration avec les unités et facultés, a la responsabilité d'assurer une formation continue sur les CI pour tous les membres de l'institution et d'assurer que la politique soit clairement interprétée et que les procédures soient bien assimilées et conformément appliquées.*

- Il s'agit d'apprendre à reconnaître la diversité des problématiques qui engendrent des CI, certaines n'étant pertinentes qu'à des membres universitaires particuliers.

- Développer une diversité d'outils de formation sur les CI applicables à des situations, des contextes et des publics différents.
- Assurer une formation régulière et continue ainsi que le soutien, par l'enseignement, afin de pourvoir au perfectionnement des compétences dans la résolution de problèmes.

Conséquences de ne pas respecter la PCI

Article 12 : *Tout membre universitaire doit déclarer les CI qui le concernent en lien avec son statut ou sa fonction. La négligence de déclarer un CI ou la persistance et la non-résolution d'un CI pourraient amener des conséquences et des sanctions déterminées par la convention d'emploi du membre ou le Conseil universitaire sur la gestion des CI.*

Exemples de procédures pour les membres

Chercheurs

1. Si un chercheur croit qu'il y a CI dans son projet de recherche, ou qu'un CI capable de porter atteinte à sa personne ou à son projet est envisageable, il doit premièrement le divulguer à son supérieur.

2. Le chercheur en collaboration avec son supérieur (parfois accompagné par un comité) doit évaluer la situation. Pour ce faire, on doit :
    - Identifier les membres qui sont ou qui pourraient être touchés par des CI.
    - Évaluer le niveau de risque et la nature du risque encouru par chacun des membres
    - Évaluer s'il y a des risques liés à la réputation de l'individu ou de l'institution
    - Réviser les lignes directrices de l'organisme subventionnaire afin d'assurer que la gestion des CI est faite selon les règles établies.

3. Trouver une méthode de gestion appropriée. Habituellement, lorsqu'on est en présence de participants humains, ces derniers doivent être informés de tout CI. S'ils ne sont pas informés, il faut nécessairement être en mesure de justifier ce choix.

4. Dans le cas où un projet inclut des participants humains, un plan de gestion des CI ainsi qu'une attestation signée par le cadre qui a géré les CI doivent être envoyés au CÉR sectoriel avec la demande de projet de recherche pour évaluation éthique. Le CÉR évalue alors le projet comme un tout, ce qui inclut les méthodes de gestion de CI.

Étudiants

1. Si un étudiant croit qu'il est dans un CI, ou qu'il est (ou peut être) touché par le CI d'autrui, il a la responsabilité de déclarer la situation à son supérieur. Dans le cas, ou le CI est en rapport avec le supérieur, l'étudiant peut informer le Comité universitaire de gestion des CI.

2. L'étudiant en collaboration avec le supérieur (parfois accompagné par un comité) doit évaluer la situation. Pour ce faire, on doit :
    - Identifier les membres qui sont ou qui pourraient être touchés par le CI.
    - Évaluer le niveau de risque et la nature du risque encouru par chacun des membres.
    - Évaluer s'il y a des risques liés à la réputation de l'individu ou de l'institution.

3. Trouver une méthode de gestion appropriée en collaboration avec l'étudiant.

Administrateurs

1. Si un membre de l'administration croit qu'il y a un CI (individuel ou institutionnel), ou croit qu'il est directement touché par un CI, il doit premièrement le déclarer à son supérieur.

2. Les cas de CI institutionnel seront directement déclarés au Comité universitaire de gestion des CI.

3. Le membre de l'administration en collaboration avec son supérieur (parfois accompagné par un comité) doit évaluer la situation. Pour ce faire les membres doivent :
    - Identifier les membres qui sont ou qui pourraient être touchés par le CI.
    - Évaluer le niveau de risque et la nature du risque encouru par chacun des membres.
    - Évaluer s'il y a des risques liés à la réputation de l'individu ou de l'institution.

4. Trouver une méthode de gestion appropriée.

Conclusion

The evolving university environment and broader academic landscape — which has been marked by increasing collaborations with industry, growing pressures for commercialization, and complex interpersonal dynamics — offers new opportunities for innovation, funding, and societal impact. But it also introduces complex ethical challenges, chief among them the management of conflicts of interest (COI) on the part of researchers and institutions, amongst others.

This book compiles the results of more than a decade of empirical research and policy analysis by a research team at the Université de Montréal. It offers a nuanced and practical approach for understanding and managing COI in the university context. At its core, the book challenges the simplistic and often pejorative view that COI is synonymous with corruption or misconduct. Instead, it is argued that COI should be seen as a pervasive and often unavoidable feature of academic life, arising not only from financial entanglements but also from personal, institutional, and professional relationships. Whether in the classroom, the laboratory, or the meeting room, COI can subtly influence decisions, shape research agendas, and affect the credibility of academic institutions, especially when situations are ignored or poorly managed.

Through detailed case studies, policy analyses, and practical decision-making tools, the book provides a roadmap for institutions seeking to balance academic freedom, individual responsibility, and public accountability. Weaving through these texts is the argument that effective COI management requires more than rigid policies or punitive measures. While formal "hard" mechanisms such as policies and regulations are essential for setting boundaries and ensuring accountability, they are insufficient on their own. Equally important are "soft" mechanisms: education, self-awareness, open dialogue, and an ethical organizational culture anchored in reflection and transparent decision-making.

Key contributions

- **Beyond financial COI**: While financial conflicts — especially in clinical research and technology transfer — have received significant attention, the book highlights the equally important, yet often overlooked, non-financial COIs. These include biases in student supervision, peer review, authorship, and institutional decision-making. The nuanced treatment of these issues broadens the ethical lens through which COI is understood.
- **Case-based learning:** Through detailed case studies — ranging from professors assigning their own textbooks to students, to researchers navigating industry-funded research in vulnerable communities — the book illustrates the real-world dilemmas faced by academics. These narratives humanize the abstract concept of COI and provide a pedagogical foundation for ethics education and policy development.
- **Policy innovation and institutional reform:** A model institutional COI policy, developed for the Université de Montréal, is presented as an innovative approach to making COI management meaningful for all members of an academic institution. Also included are practical procedures for managing COI in the context of thesis juries, research collaborations, and administrative roles.
- **Soft and hard mechanisms:** A dual approach to COI management is advocated, combining "hard" mechanisms (formal policies, disclosure requirements, institutional

oversight) and "soft" mechanisms (ethics training, self-reflection, peer dialogue, and a culture of integrity). This balanced approach recognizes the limitations of rule-based governance and the importance of ethical agency.

- **Sectoral and disciplinary diversity:** The book addresses COI across a wide range of academic domains, including public health, the biosciences, the humanities and social sciences. It also explores the unique challenges faced by students, early-career researchers, administrators, and journal editors. This inclusivity enhances the book's relevance and applicability across the university ecosystem.

Implications for academic stakeholders

- **For professors:** The book underscores the importance of self-awareness, transparency, and fairness in mentoring relationships. It encourages faculty to reflect on how their interests — academic, financial, or personal — may influence their judgment and to adopt proactive strategies for managing COI in their professional activities.
- **For students:** Graduate students are often caught in power asymmetries that expose them to COI situations. The book can empower students to recognize these dynamics and provides guidance on navigating these situations ethically.
- **For researchers and journal editors:** The book highlights the ethical responsibilities of researchers and editors in ensuring the integrity of the research and publication processes. It advocates for transparent disclosure practices, rigorous peer review, and the avoidance of undue influence from sponsors or collaborators.
- **For administrators and policy makers:** Institutional leaders are called upon to move beyond compliance-driven approaches and to foster an ethical organizational culture. The book offers concrete tools for policy development and implementation, including models for COI policies and procedures.
- **For institutions**: Universities must recognize that COI is not merely an individual problem but an institutional challenge, and a serious risk if poorly managed or ignored. The book calls for systemic reforms, including ethics education, decentralized governance, and mechanisms for monitoring and accountability.

Final reflections

In an era where universities are increasingly expected to be entrepreneurial, globally competitive, and socially responsive, the ethical stakes of academic work have never been higher. Conflicts of interest are not unethical practices to be eliminated, but realities to be managed with care, humility, and integrity. This book offers a roadmap for doing just that. It invites the reader to reimagine the university not as a site of moral purity, but as a complex ethical community — one that must continually negotiate the tensions between knowledge, power, and responsibility. The tools presented in the book aim to empower individuals to recognize and navigate COI in real time, fostering a more resilient and ethically grounded academic environment. Tying the book together is an emphasis on transparency, proportionality, and context-sensitive judgment in managing COI, and the need for sustained investment in ethics training and institutional capacity-building.

Ultimately, the book calls for a shift in how universities conceptualize and respond to COI. Rather than treating it as an aberration to be eradicated, COI should be seen as a structural feature of academic life that must be managed with integrity, humility, and care. The book challenges all members of the academic community to engage critically with their own practices, to support one another in ethical decision-making, and to build institutions that are not only excellent, but also just, transparent, and trustworthy. By embracing this more sophisticated approach to dealing with COI, universities can safeguard their credibility, support their members, and fulfill their public mission in an increasingly complex world.